Research Project Portfolio

University of Lincoln

School of Psychology

College of Social Science

Doctorate in Clinical Psychology

2020

Behavioural Activation for Low mood in Multiple Sclerosis

Lloyd Louis Oates, BSc. (Hons), MSc. PGCert

Submitted in part fulfilment of the requirements for the

Doctorate in Clinical Psychology

Portfolio abstract

Purpose: People with secondary progressive multiple sclerosis (MS) experience high rates of depression. Behavioural activation may represent an accessible therapeutic intervention for this group. We aimed to: (a) examine preliminary evidence of efficacy of a behavioural activation intervention, for people with secondary progressive MS experiencing low mood; (b) understand the feasibility of recruiting, retaining, and delivering the intervention; (c) explore whether/how the intervention has a positive impact on mood, fatigue, and quality of life (QoL) using process measures; and (d) understand participants' experience of the intervention.

Research method/design: A mixed-method multiple single-case experimental design was used to investigate the effectiveness of a five-session behavioural activation intervention on depression for people with secondary progressive MS. An AB design was used, and intervention was delivered after establishing a stable baseline for depression on the Patient Health Questionnaire 2. Depression was measured using the Hospital Anxiety and Depression Scale – depression subscale and activation was measured using the Behavioural Activation for Depression Scale – Short Form. The intervention was delivered using an initial face-to-face session followed by telephone or Skype-delivered sessions. Data were analysed using visual analysis (conservative dual-criterion and percentage exceeding the median) and reliable and clinically significant change analysis. Post-intervention change interviews were completed and analysed using framework analysis.

Results: Eight people were recruited, of which six established a stable baseline and proceeded to intervention. Five participants completed the intervention and one participant withdrew. Five participants, including the participant who withdrew, completed change interviews. Systematic reduction in depression was observed in three of five completers and

reliable and clinically significant reduction was observed in two of these three participants. Three of five participants demonstrated highly effective treatment (≥.9) and two participants demonstrated moderately effective treatment (0.7-0.9). Systematic increase in activation was observed in two of five completers and reliable change was observed in one participant. In most cases, in change interviews, participants reported benefits from the intervention and that it was acceptable, even in the face of competing demands. No changes were observed in fatigue or physical components of health related QoL. Reliable change was observed in two participants for mental health related QoL.

Conclusion: There was some evidence to suggest that behavioural activation for people with secondary progressive MS led to a reduction in depressive symptoms when engagement in positively reinforcing behaviour increased. Changes in fatigue or physical health QoL were not observed suggesting that engaging in behavioural activation does not worsen fatigue.

Acknowledgements

I would like to thank my research supervisors Professor Roshan das Nair and Dr Nima Moghaddam. They have shared so much of their knowledge and expertise. They have supported, encouraged, and contained me during the research and never tired of my questions; which only encouraged my enthusiasm for the project.

I would like to thank my participants, without you, none of this would have been possible. Thank you to Dr Nikos Evangelou and the other clinicians in the Department of Neurology, and to the MS Society support groups for their continued support in the research and recruitment.

To my friends, thank you for your support, for listening and understanding, whilst I undertook this process. For my cohort, thank you for helping to motivate me and lending your ears when needed.

A huge thank you to my mum and dad, without you this would not have been possible, you were always about to take away additional stressors allowing me to focus on the doctorate – thank you for letting me become a lodger once again. Additionally, thank you to Em and James for providing humorous relief.

Finally, to my wife Katie, for everything you have done, sacrificed, and contended with. Without you, I would not have got here. You have always encouraged, supported, and believed in me. Thank you for your love, help, and containment which has driven me on the hard days. I hope I've made you all proud.

Statement of Contribution

Lloyd Oates contributed to the project design, applying for ethical approval, writing the review of the literature, consenting participants, delivering the intervention, data collection, scoring questionnaires and assessments, data entry, analysis, and the write up of the project.

Professor Roshan das Nair (RdN) and Dr Nima Moghaddam (NM) assisted with project design and application for ethical approval. Dr Nikos Evangelou and the neurology team assisted with participant recruitment. Christopher Meek (CM), Trainee Clinical Psychologist, conducted change interviews. Dr Nima Moghaddam completed the fidelity checks. Professor Roshan das Nair and Dr Nima Moghaddam assisted with data analysis and trial write-up.

Table of Contents

List of Tables and Figures

Behavioural activation treatment for depression in individuals with neurological conditions: A systematic review

Lloyd L. Oates,[1,2] Nima Moghaddam,[1] Nikos Evangelou,[3] and Roshan das Nair[4,5]

1. Trent Doctorate in Clinical Psychology, University of Lincoln, UK.
2. Lincolnshire Partnership NHS Foundation Trust, Lincoln, UK.
3. Division of Neurosciences, University of Nottingham, Nottingham, UK.
4. Institute of Mental Health, Nottingham, UK.
5. Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, UK.

Lloyd Oates - Email: 16662517@students.lincoln.ac.uk Telephone: +44 (0)1522 886029;
Nima Moghaddam - Email: NMoghaddam@lincoln.ac.uk Telephone: +44 (0)1522 886029
Nikos Evangelou - Email: nikos.evangelou@nottingham.ac.uk Telephone: +44 (0) 115 8231449
Roshan das Nair - Email: Roshan.Dasnair@nottingham.ac.uk Telephone: +44 (0) 115 74 84240

Correspondence to: Professor Roshan das Nair, Professor of Clinical Psychology & Neuropsychology, B19, Institute of Mental Health, Jubilee Campus, University of Nottingham, Nottingham, NG7 2TU, UK.
Email: *Roshan.Dasnair@nottingham.ac.uk*

DOI: 10.1177/0269215519896404 https://doi.org/10.1177/0269215519896404
Clinical Rehabilitation
Mental Health Review Journal

Abstract

Objective: To evaluate the effectiveness of behavioural activation interventions for people with neurological conditions with co-morbid depression, and explore content and adaptations.

Data sources: PsycINFO, MEDLINE, CINAHL, AMED, and EMBASE databases were searched on the 19/11/19. Reference lists of selected full-texts were screened by title.

Review methods: We included peer-reviewed studies, published in English that used behavioural activation for treatment of depression in adults with a neurological condition. Single case reports, reviews, and grey literature were excluded. Methodological quality was assessed by two authors independently and quality was appraised using Critical Appraisal Skills Programme checklists.

Results: From 2714 citations, 10 articles were included comprising 590 participants. Behavioural activation was used to treat depression in people with dementia (*n*=4), stroke (*n*=3), epilepsy (*n*=1), Parkinson's disease (*n*=1), and brain injury (*n*=1). Sample size ranged from 4 to 105 participants. There were seven randomised-controlled studies, however, no studies compared behavioural activation to an alternative psychological therapy. The effect sizes varied between small and large in the studies where effect size could be calculated (*d*= 0.24-1.7). Methodological quality of the included studies was variable. Intervention components were: identifying and engaging in pleasurable activities, psychoeducation, and problem solving. Adaptions included: delivering sessions via telephone, delivering interventions via primary caregivers, and giving psychoeducation to caregivers.

Conclusion: The effectiveness of behavioural activation in randomised-controlled trials varied from small to large (*d*= 0.24-1.7) in reducing depression. The content of behavioural activation was comparable to established treatment manuals. Adaptations appeared to support individuals to engage in therapy.

Review registration: PROSPERO 2018, CRD42018102604.

*Key words***:** Neurological conditions, depression, behavioural activation, behavioural therapy, activity scheduling

Behavioural activation treatment for depression in individuals with neurological conditions: A systematic review

Introduction

People with neurological conditions experience higher rates of depression than those in other patient groups without neurological conditions [1]. Decreased social activities contribute to the continuation and exacerbation of depression through a loss of contact with contingencies that were previously reinforcing and mood enhancing [2]. Conversely, engagement in social and leisure activities for people with multiple sclerosis promotes positive mood and wellbeing [3, 4]. With depression and reduced or declining physical abilities (common in many neurological conditions), individuals find it difficult to identify with and engage in activities that have pleasurable or reinforcing consequences [2].

In the UK, National Institute of Health and Clinical Excellence recommends the use of cognitive behavioural therapy for treating depression in individuals with chronic physical health problems (including neurological conditions) [5]. However, cognitive-behavioural therapy is not best suited for people with neurological conditions [6], because many have cognitive difficulties that may make accessing and engaging with cognitive-behavioural therapy difficult [7]. Therefore, adapting psychological therapies to better consider the interaction of co-morbid psychological and physical conditions may be more acceptable to people with neurological/physical health conditions [8].

Behavioural activation is a type of psychological therapy that encourages individuals with depression to engage in activities they have been avoiding. Individuals define goals and activity schedules [9]. Behavioural activation is a relatively simple, easy to understand, intervention that does not require a highly trained therapist or complex skills from the patient [10], and may be suitable for individuals with cognitive and physical difficulties.

In non-neurological populations, the behavioural activation component of cognitive-behavioural therapy is as effective alone compared to when used in combination with cognitive aspects [11] – and has been found to be as effective as antidepressant medication [12]. A meta-analysis of activity scheduling (a type of behavioural activation) interventions for the treatment of depression found a pooled effect size (*d*) of 0.87, favouring activity scheduling over waitlist or placebo controls or alternative psychological therapies (95% CI: 0.60~1.15) [13]. Behavioural activation is also considered cost-effective for depression [14]. However, the evidence for the effectiveness of behavioural activation in people with neurological conditions is inconclusive.

Therefore, this review aimed to: (i) report the evidence of the effectiveness of behavioural activation interventions for individuals with neurological conditions with co-morbid depression, with outcomes of interest being mood, function, activity, and quality of life; (ii) describe the content of behavioural activation interventions; and (iii) identify the adaptations made to the behavioural activation intervention specifically for people with neurological conditions.

Method

We followed the PRISMA-P 2015 guidelines [15] and the protocol was prospectively registered on PROSPERO (CRD42018102604).

The following online databases were searched: Medline (1970-present), CINAHL (1970-present), PsycINFO (1970-present), EMBASE (1980-present), and AMED (1980-present). The last search was completed on 19/11/2019. The following keywords were used: Behavioural activation, behaviour therapy, activity scheduling, depression, and neurological conditions. We used variations of these terms including medical subject headings (MeSH) where available. For a complete list of the search terms please refer to Appendix A. Terms

were ‘exploded’ and used singularly or in conjunction with similar terms based on the database being searched. The reference lists of the selected full-texts were screened by title, as an additional way of identifying relevant articles.

Included studies were: Peer-reviewed, quantitative or qualitative, and published in English. Studies were required to include: (a) behavioural activation for treatment of depression (clinician confirmed diagnosis or scoring above defined thresholds on validated depression measures); (b) adults (≥16 years) with a neurological condition, defined as a condition or disease of the brain, as a result of illness or injury. Studies using behavioural therapy were included where the use of activity scheduling and monitoring was of primary focus; which was defined as the targeting of behavioural avoidance and increasing contact with environmental positive reinforcement. We were primarily interested in clinical effectiveness of the intervention on the patient, but we also included outcomes that related to the care-giver. We excluded articles that were policy papers, books, theses, or conference proceedings.

Data extraction was completed by the first author and accuracy was checked by the other authors. Table 1 summarises the data extracted. Following the database searches, results were transferred to Microsoft Excel and duplicates were removed. The first author screened titles and abstracts, before reviewing full text articles. Data extraction was completed using a predefined template informed by the reader's guide to critical appraisal of cohort studies [16-18] (for the template headings please see Appendix B).

Following PRISMA guidance [16-18], the first and one other author independently assessed the methodological quality of each included article. Discrepancies were resolved

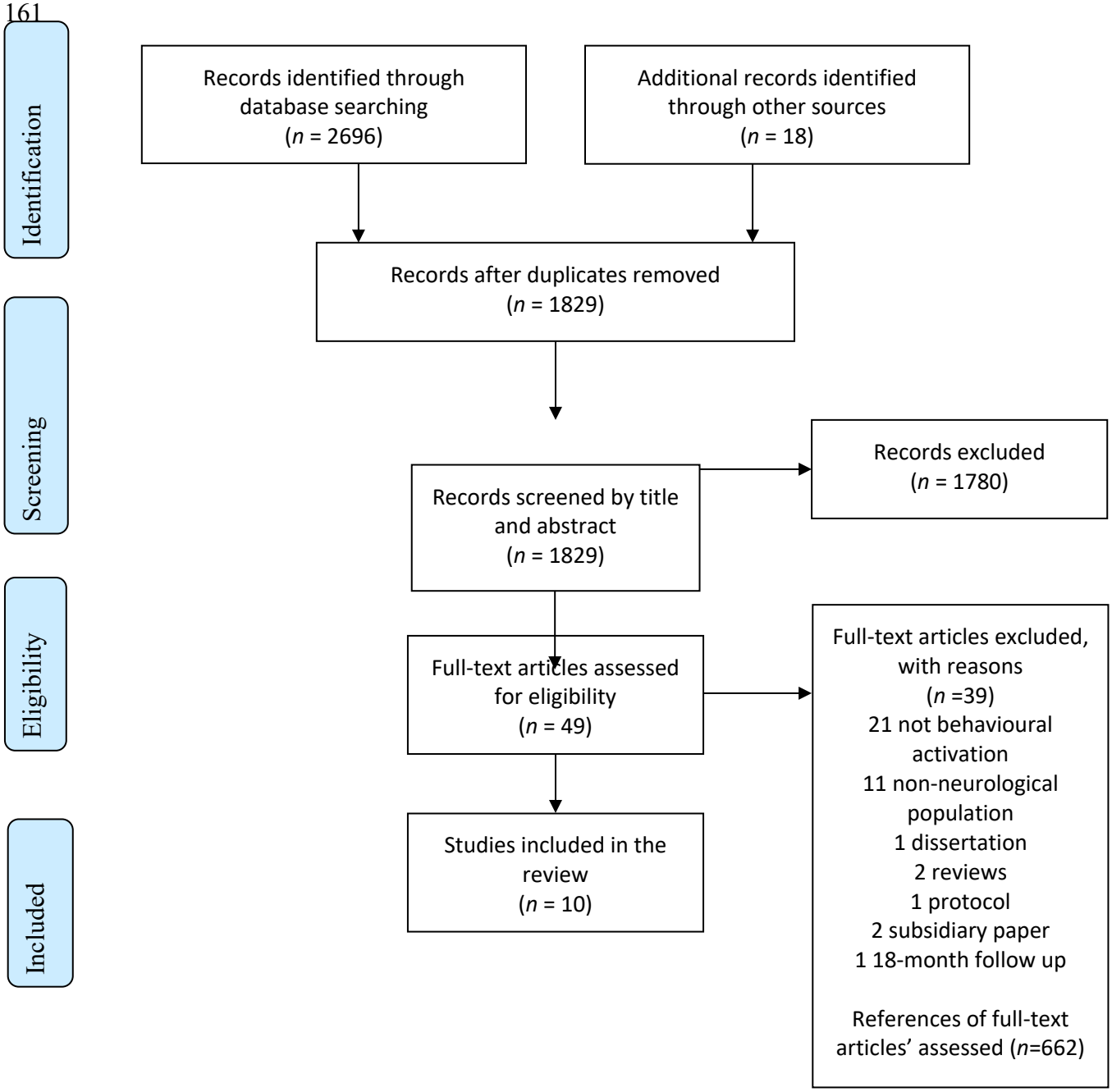
through discussion. The quality appraisal framework selected was informed by the study design of the included articles: Critical Appraisal Skills Programme Randomised Controlled Trials checklist [19], cohort studies checklist [20], qualitative checklist [21], and Mixed Methods Appraisal Tool– Version 2011 [22].

A narrative summary for data analysis was conducted due to the low number of articles identified. A meta-analysis was not considered because we only had a small number of studies, with considerable heterogeneity in terms of study designs, outcome measures, and measurement time-points. Therefore, to compare and synthesise effectiveness data, effect size estimates were used (with effect size determined from study data when not reported). Where multiple depression measures were used the primary measure was used. Through conversion into standardised between-condition effect-sizes, we treat studies as comparable with respect to the comparison condition (e.g., that usual care is similar across studies); however, if comparators (e.g., forms of 'usual care') differ systematically across studies, then this assumption (of transitivity) would be violated: the treatment effect will not be defined independently of individual comparators (i.e., there will be a treatment-by-study interaction).

Results

Initial database searches identified 2714 articles, 49 full text articles were considered for inclusion, and 10 articles (with 590 participants) met our inclusion criteria. Figure 1 is the PRISMA flow diagram.

Figure 1. PRISMA Flow Diagram



All included articles were quantitative intervention studies: seven randomised-controlled trials [23-29], one cohort study [30], and two multiple baseline experimental design studies [31, 32]. The articles were published between 1991 and 2019, based on studies from the USA [23, 26-32], UK [24] and Australia [25]. The components and format of the behavioural activation interventions are summarised in Table 1, which also describes the clinical context of each intervention, and the comparator groups (where used).

Table 1

Summary of the extracted data

Study number, author(s), date, and country	[31] Feliciano, Steers, Elite-Marcandonatou, McLane, & Areán (2009), USA	[23] Teri, Logsdon, Uomoto, & McCurry (1997), USA	[25] Travers (2017), Australia	[32] Teri and Uomoto (1991), USA	[24] Thomas, Walker, Macniven, Haworth, & Lincoln (2013), UK	[27] Kirkness, Cain et al. (2017), USA	[28] Mitchell, Veith, et al. (2009), USA	[26] Ciechanowski, Chaytor et al. (2010), USA	[30] Butterfield, Cimino, et al. (2017), USA	[29] Hart, Vaccaro, Collier, Chervoneva & Fann (2019), USA
Method, recruitment, & depression identification method	Single case experimental design. Pre-post-test. Non-concurrent multiple baseline design. Community: CSDD	RCT. Community: Caregiver report, Clinical interview, CSDD, HDRS	Pilot RCT. Interview with care staff. Community: GDS	Single case experimental design. Pre-post-test (*n*=2), AB (*n*=1), ABAB (*n*=1). Community: DSM-III criteria, HDRS	RCT. Community: SADQH-10, PSADQH-21	RCT. Community: Screen: GDS ≥11; Study start: Clinical interview, DSM-IV criteria, HDRS	RCT. Community: Screen: GDS ≥11; Study start: Clinical interview, DSM-IV criteria, HDRS	RCT. Community: PHQ-9	Experimental design. Pre-/post- test. Community: GDS	RCT. NR. Patient Health Questionnaire-9
Sample characteristics	**Population:** Dementia **Total:** *n*=11 **Age (Years):** Range =78-95, *M*=85.6 **Female gender:** *n*=10 (91%) **Intervention:** Masters-level clinicians *n*=2	**Population**: Dementia **Total**: *n*=72 participant-caregiver dyads; BT-PE *n*=23; BT-PS *n*=19; Usual care *n*=10; Wait list control *n*=20 **Age (Years)**: Range = not reported, *M*=76.4 (*SD*=8.2); BT-PE *M*=72.8 (*SD*=8.2); BT-PS *M*=78.5 (*SD*=7.9); Usual care *M*=79.5 (*SD*=6.9), Wait list control *M*=76.8 (*SD*=8.2); Caregiver *M*=66.9 (*SD*=11.0) **Female gender**: *n*=34 (47%); BT-PE *n*=16 (70%); BT-PS *n*=5 (26%); Usual care *n*=6 (60%);	**Population:** Dementia **Total:** *n*=18; BT *n*=10; Walking and talking *n*=8 **Age (Years):** Range = not reported, *M*=86.5 (*SD*=8.8); BT *M*=87.2 (*SD*=7.7); Walking and talking *M*=85.5 (*SD*=10.9) **Female gender:** *n*=16 (89%); BT *n*=8 (80%);	**Population:** Dementia **Total:** *n*=4 patient caregiver dyads **Age (Years):** Range=74-81, *M*=78 (*SD*=3.16); Caregiver range=32-47, *M*=38.5 (*SD*=7.23) **Female gender:** *n*=2 (50%); Caregiver *n*=2 (50%) **Intervention:** Psychologist (*n*=1); Caregiver (*n*=4)	**Population:** Stroke with aphasia **Total:** *n*=105; BT *n*=51; Usual care *n*=54 **Age (Years):** Range=29-94, *M*=67.0 (*SD*=13.5); BT *M*=68.5 (*SD*=13.1); Usual care *M*=65.5 (*SD*=13.9) **Female gender:** *n*=39 (37%); BT *n*=22 (43%); Usual care *n*=17 (31%) **Intervention:** Assistant psychologists (*n*=8)	**Population:** Stroke **Total:** *n*=100; Intervention telephone *n*=37; Intervention face-to-face *n*=35; Usual care *n*=28 **Age (Years):** Range=23-88, *M*=NR; Intervention telephone =31-85, *M*=61.7; Intervention face-to-face =23-83, *M*=58.5 (*SD*=NR); Usual care =32-88, *M* = 60.7 (*SD* = NR) **Female gender:** *n*=50 (50%); Intervention telephone *n*=18 (49%);	**Population:** Stroke **Total:** *n*=101; Intervention *n*=48; Usual care *n*=53 **Age (Years):** Range 25-89, *M*=NR; Intervention =25-88, *M*=57 (*SD*=NR); Usual care =29-88, *M*=57 (*SD*=NR) **Female gender:** *n*=40 (40%); Intervention *n*=19 (40%); Usual care	**Population:** Epilepsy **Total:** *n*=80; BT *n*=40; Usual care *n*=40 **Age (Years):** Range=NR, *M*=43.9 (*SD*=11.0); BT *M*=43.4 (*SD*=11.0); Usual care *M*=44.4 (*SD*=11.1) **Female gender:** *n*=42 (53%); BT *n*=19 (48%); Usual care *n*=23 (58%) **Intervention:** Social workers *n*=3	**Population:** Parkinson's disease **Total:** *n*=34 (27 analysed). *n*=27 spouse/family members **Age (Years):** Range=44-86, *M*=66 (*SD*=10.7) **Female gender:** *n*=5 (19%) **Intervention:** Principle investigator (*n*=1), students (*n*=3)	**Population:** Brain Injury **Total:** *n= 65;* BA intervention *n*=43, Motivation intervention *n*=22. Attrition *n*=6 (BA intervention = 5, Motivation intervention =1) **Age (Years):** Range NR, BA intervention *M* 40.4, Motivation intervention *M* 38.5. **Female gender:** 12 (20.3%). BA intervention *n*=8 (21%), Motivation intervention *n*=4 (19%). **Intervention:** Researchers

		Wait list control *n*=7 (35%); Female caregiver *n*=50 (69%) **Intervention**: Psychologist (*n*=1)	Walking and talking *n*=8 (100%) **Interventio n:** Care staff (*n*=NR) **Interview:** Staff (*n*=14)			Intervention face-to-face *n*=18 (51%); Usual care *n*=14 (50%) **Intervention:** Study therapist (*n*=1)	*n*=21 (40%) **Interventio n:** Study therapist (*n*=1)			
Intervention and format	**Manualised:** No **Components:** Identifying pleasurable activities, communicating activities to caregivers, Developing behaviour plans **Number and length of sessions:** NR **Mode of delivery:** Face-to-face **Format:** Individual **Comparator:** None	**Manualised:** Yes **Components:** Psychoeducation for caregivers, Psychoeducation, identifying activities, Activity scheduling, Activity monitoring, Caregiver problem-solving, Caregiver activity scheduling, Working with behavioural disturbances, Relapse prevention **Number and length of sessions:** 9 (1-hr) **Mode of delivery:** Face-to face. Caregiver supported by therapist **Format:** Individual **Comparator:** BT-PS, Usual care, Wait list control	**Manualised :** Yes (BE-ACTIV) **Component s:** Involving activities staff, 3-hr staff training component, identifying activities, Activity scheduling, increasing activities, Behavioural managemen t **Number and length of sessions:** 8 sessions (NR) **Mode of delivery:** Face-to-face **Format:** Individual **Comparato r:** Walking and talking	**Manualised:** No **Components:** Psychoeducation for patients and caregivers, identifying activities, Engagement in activities, Activity tasks supported by caregivers **Number and length of sessions:** 8 (1-hr). Patient 3 of 8 sessions, caregiver 8 of 8 sessions. **Mode of delivery:** Face-to-face **Format:** Individual and caregiver **Comparator:** None	**Manualised:** Yes **Components:** Maximising mood-elevating activities, Psychoeducation, Activity monitoring, Activity scheduling, Grading tasks, Communication adaptations **Number and length of sessions:** <20, *M*=9.07 (*SD*=2.36), range 3-18 (1-hr) **Mode of delivery:** Face-to-face **Format:** Individual **Comparator:** Usual care	**Manualised:** Yes **Components:** Psychoeducation, Identifying activities, Activity scheduling, Problem-solving, Skills review **Number and length of sessions:** 6 (10-80 min). Telephone intervention *M*=26 min, face-to-face *M*=38 min **Mode of delivery:** Group 1, telephone; Group 2, face-to-face **Format:** Individual **Comparator:** Usual care	**Manualised :** Yes **Component s:** Psychoeduc ation, Identifying activities, Activity scheduling, Problem-solving, Skills review **Number and length of sessions:** 9 (NR) **Mode of delivery:** Face-to-face **Format:** Individual **Comparato r:** Usual care	**Manualised:** Yes (PEARLS) **Components:** Activity scheduling, Activity monitoring, Behavioural activation, Problem-solving, Focus on social and physical activation **Number and length of sessions:** 8 (50 min) **Mode of delivery:** Face-to-face, telephone **Format:** Individual **Comparator:** Usual care	**Manualised:** Yes (BATD) **Components:** Goal setting, Activity scheduling, Activity monitoring **Number and length of sessions:** 6 (2-2.5-hr, n=1; 10-20 min. *n*=5) **Mode of delivery:** Face-to-face (*n*=1), telephone (*n*=5), automated web reminders **Format:** Individual **Comparator:** None	**Manualised:** Scripted sessions **Components:** Psychoeducation, identifying activities, activity scheduling, implementation intentions **Number and length of sessions:** Face-to-face (*n*=1), telephone (*n*=1), Text messages (*n*=8) **Mode of delivery:** Face-to-face and telephone **Format:** Individual **Comparator:** Motivation interventions

Measurement time points and measures. Effect size*	**Pre- and post-Intervention:** CMAI-Long form, MAS, MMSE, ADL, CSDD, PES, RAISD. **Effect size:** NR/insufficient data	**Pre- and post-Intervention:** CSDD, HDRS, MMSE, DRS, RIL **Caregiver:** HDRS **Effect size:** Depression: BT-PE & BT-PS effect size ranged from *d*=0.9-1.7 on the HDRS and CSD BT-PE BDI *d*=0.4; BT-PS BDI *d*=1.0 Caregiver: HDRS [F(3,66) = 4.73, p < .01] **6-month follow up** Significant effects on reduced sample maintained.	**Pre- and post-Intervention:** GDS, QOL-AD-nursing home, PES-nursing home, MMSE. **Effect size:** NR/insufficient data	**Pre- and post-Intervention daily:** HDRS, PES-elderly version (caregiver to patient), MMSE, **Caregiver:** HDRS **Effect size:** N/A	**3- and 6-months post-randomisation:** SADQH-10, SADQH-21, NLQ, CSI, SST, FAST, BI, VASES **Effect size:** Depression: Three-month d_{Korr} = 0.542; Six-month d_{Korr} = 0.771	**Baseline, 8-weeks (post-intervention), 21-weeks, 12-months:** HDRS, NIHSS, GDS, BI, SIS **Effect size**: Depression: 8-week *d*= 0.243; 21-week *d*= 0.053; 12-month *d*= 0.104	**Baseline, 9-weeks (post-intervention), 21-weeks, 12-months:** HDRS, NIHSS, GDS, BI, SIS **Effect size:** Depression: 9-week *d* = 1.172; 21-week *d*= 0.341; 12-months *d*= 0.484; 24-month *d*= 0.398	**Baseline, 6- and 12-months:** HSCL-20, QOLIE-31 **Effect size:** Depression: 6-month *d*= 0.38; 12-month *d*= 0.704	**Baseline, post-intervention, 1-month follow-up:** AES, GDS, UPDRS, PDQ-39 **Caregiver:** ZBI **Effect size:** Depression: *d*= 0.70; Apathy: *d*= 0.77; Quality of Life: *d*= 0.5	**Pre-, mid-, and post-intervention:** EROS, BADS **Effect size:** NR
Summary points and key findings	Only four participants were depressed - change was observed in two of the four. One participant had a clinically significant change (a 11-point drop) and one participant had a small decrease in score that was not clinically significant. PES was completed with eight participants (73%) the remaining 3 were completed by family members or care staff.	Participants in both behavioural groups showed significant improvement in depressive symptoms compared to those in the usual care and wait list control. Caregiver depression improved on the HDRS. 25 participants (60%; 95% CI = [.45, .74]) in the active treatment conditions showed clinically significant improvement. At six-months participants and	The average number of activities completed by the intervention group increased from baseline (*z*= 2.82, *p*< 0.005). Quality of life improved in the walking and talking group (*p*=0.04) from baseline. Qualitative	Significant positive relationship between depressed mood and duration and frequency of activities. Less depressed mood was associated with a longer duration and higher frequency of activities. The duration of activities may be more important to mood than frequency of activities. No baseline data	Allocation to behavioural activation compared to usual care significantly predicted better self-reported mood, self-esteem and observer-rated mood three months after randomisation. No significant effects for behavioural activation on caregiver strain or leisure activities (*p* values not reported). Both participants and caregivers reported higher satisfaction	Intervention groups were combined and had a mean reduction on HDRS scores of 39% (40% face-to-face and 38% telephone) compared to 33% reduction in usual care at 8 weeks, no significant difference. The modality of intervention (face-to-face and telephone) were comparable for outcomes.	Mean decrease in depression was significantly greater at 1-year compared to control.	Intervention resulted in significantly greater depressive symptom reduction over 12-months compared with usual care.	Apathy and depression scores were significantly different with a large effect size. Depression scores were maintained one month follow up.	The difference between conditions was not significant for 8-week changes or 4-week changes for any outcome measure.

		caregivers in active treatment conditions (BT-PE & BT-PS) maintained significant improvement.	comments: 93% of staff reported benefits for the intervention group. They reported improved mood in four residents and greatly reduced anxiety in one resident, from baseline.	was collected for 50% of the participants Caregiver depression: Caregivers with depression at pre-treatment (*n*=2) showed a reduction in HDRS and BDI scores.	with emotional support, communication support, and hospital and community services.					

Note: * all favoured intervention. NR = Not reported.
ADL; Katz Basic Activities of Daily living scale, AES; Apathy Evaluation Scale, BADS; Behavioural Activation for Depression Scale, BATD; Brief Behavioural Activation Treatment for Depression, BDI; Beck Depression Inventory, BI; Barthel Index, CMAI; Cohen -Mansfield Agitation Inventory-Long form, BT-PE; Behavioural therapy pleasant events, BT-PS; Behavioural therapy problem-solving, CSDD; Cornell Scale for Depression in Dementia, CSI; Carer Strain Index, DRS; Dementia Rating Scale, DSM-III; Diagnostic and Statistical Manual of Mental Disorders-III, EROS; Environmental Reward Observation Scale, FAST; Frenchay Aphasia Screening Test, GDS; Geriatric Depression Scale, HDRS; Hamilton Depression Rating Scale, HSCL-20; Hopkins Symptom Checklist – 20, MAS; The motivation assessment scale, MMSE; Mini–Mental State Examination, NIHSS; National Institutes of Health Stroke Scale score, NLQ; Nottingham Leisure Questionnaire, PDQ-39; Parkinson's Disease Quality of Life, PEARLS; Program to Encourage active, Rewarding Lives for Senior, PES; The pleasant events schedule, PHQ9; Patient Health Questionnaire-9, QOL-AD; Quality of life - Alzheimer's disease, QOLIE-31; Quality of life in Epilepsy – 31, RAISD; Reinforcer assessment for individuals with severe disabilities, RIL; Record of Independent Living, SADQH-10; Stroke Aphasic Depression Questionnaire Hospitals-10 item, SADQH-21; Stroke Aphasic Depression Questionnaire Hospitals-21 item, SIS; Stroke Impact Scale, SST; Sheffield Screening Test, UPDRS; Unified Parkinson's Disease Rating Scale, VASES; Visual Analogue Self-Esteem Scale, ZBI; Zarit Burden Inventory.

The quality of the studies, as seen in Table 2, was variable. All had a clearly stated aim and identified their target sample. Participant demographics were adequately detailed in almost all studies, but one [32]. Studies and sample representativeness varied from low to high. Sample sizes ranged from 4 to 105 participants [24, 32].

The quality of reporting of the studies also varied. In randomised-controlled trials the method of randomisation was reported in all but one study [23], with most studies using computer generated algorithms [24-30, 32]. In five randomised-controlled trials assessors were blinded to participant group allocation [23, 26-29]; in one study assessors were only blinded to secondary measures [24]; and in one study there was no blinding of data collection [25]. Only two studies reported data on treatment fidelity [24, 30], with most studies collecting no or minimal data on the delivery of the intervention [23, 25-29, 31, 32]. All studies included or described data pertaining to the validity and reliability of assessment measures.

Additional sources of possible methodological biases were evident, such as reporting bias (not detailing all outcomes) [27], use of self-report methods to assess depression [23-28, 30-32], and caregivers completing depression assessments on the participants' behalf [23, 31, 32]. One study [31] used a single-case experimental design but did not report any statistical analysis or present any data for depression. One study [32] used a single-case experimental design but did not consistently establish a baseline before introducing the intervention, as recommended by multiple single case experimental design standards [33].

Table 2

Methodological characteristics of studies

Study	Clear statement of aims	Participant demographics	Sample representativeness (*n*)	Inclusion and exclusion criteria	Standardised measures	Attrition	Randomisation	Blinding	Treatment fidelity	Additional sources of bias
Feliciano, Steers [31]	Yes	Moderate	No (*n*=11), participants with depression (*n*=4)	No	Yes	Yes	N/A	N/A	No	Selection bias Reporting bias Confounders
Teri, Logsdon [23]	Yes	Yes	Yes (*n* =72)	Yes	Yes	Yes	Moderate	Yes	No	Confounders
Travers [25]	Yes	Yes	No (*n* =18)	Yes	Moderate	Yes	Yes	No	No	Selection bias Detection bias Performance bias
Teri and Uomoto [32]	Yes	No	No (*n* =4)	No	Yes	No	N/A	N/A	No	Selection bias Detection bias Confounders
Thomas, Walker [24]	Yes	Yes	Yes (*n* =105)	Yes	Yes	Yes	Yes	Moderate	Yes	
Kirkness, Cain [27]	Yes	Yes	Moderate (*n* =100)	Moderate	Yes	Yes	Yes	Yes	Moderate	Reporting bias Concurrent intervention
Mitchell, Veith [28]	Yes	Yes	Yes (*n* =101)	Moderate	Yes	Yes	Yes	Yes	No	Change scores calculated rather than absolute difference between groups
Ciechanowski, Chaytor [26]	Yes	Yes	Yes (*n* =80)	Moderate	Moderate	Yes	Yes	Yes	Moderate	
Butterfield, Cimino [30]	Yes	Moderate	Moderate (*n* =34)	Moderate	Yes	Yes	N/A	N/A	Yes	
Hart, Vaccaro [29]	Yes	Yes	Yes (*n* = 65)	Yes	Yes	Yes	Yes	Yes	Moderate	

Note. Table collates Critical Appraisal Skills Programme tools for a single point of reference

Variants of behavioural activation processes, such as activity scheduling or monitoring were used in samples with dementia [23, 25, 31, 32], stroke [24, 27, 28], epilepsy [26], Parkinson's disease [30], and brain injury [29]. Participants were recruited from nursing homes, hospital clinics and the community. The mean age range was 38.5 to 86.5 years. A number of studies recruited patient-caregiver dyads and investigated the effects of using paid and unpaid caregivers as intervention aids [23, 25, 31, 32]. Additionally, studies reported the impact of behavioural activation for patients, on caregivers' depression, quality of life, and/or perceived burden [23, 30, 32].

The following assessments were used to assess depression outcomes: The Cornell Scale for Depression in dementia [34] [23, 31], The Hamilton Depression Rating Scale [35] [23, 27, 28, 32], Stroke aphasic depression questionnaire 21-item hospital version [36] [24], Geriatric Depression Scale-12 [37] [25, 27, 28, 30], The Patient Health Questionnaire [38] [29], and the Hopkins Symptom Checklist – 20 [39] [26]. Caregiver depression was consistently assessed using The Hamilton Depression Rating Scale [35] [23, 32].

Seven studies used comparator groups; six used a two-arm design, of which, four used usual care for one arm [24, 26-28], one used a walking and talking intervention as a comparison group [25], and one used a motivation intervention [29]. Another study [23] had four arms (behavioural therapy and pleasant events, behavioural therapy and problem-solving, usual care, and waitlist control). Attrition rates were reported for all studies and ranged from 5% [25] to 27% [31].

In terms of effectiveness (aim i) eight of ten studies reported a positive outcome for behavioural activation in terms of improving depressive symptoms [23, 24, 26, 28-32]. In studies reporting effects favouring the intervention, estimable effect size ranged from $d = 0.38–1.7$ (for parity, where multiple follow-up assessments were reported, the first post-intervention

effect-estimate was selected). When the lowest quality studies were not considered (i.e., limiting to [23, 24, 26, 28]) the effect size range remained the same.

Conversely, two studies did not favour behavioural activation, reporting non-superiority for reducing depression relative to usual care (*d* at first [8-week] follow-up = 0.24, $p = 0.30$) [27] or a walking-and-talking intervention (*d* not reported, $p = 0.61$) [25].

Overall, across the six studies for which effect-sizes were estimable [23, 24, 26, 27, 28, 30 23, 24, 26, 27, 28], effects of behavioural activation ranged widely at first follow-up (post-intervention): from small-to-large magnitude (*d*s = 0.24–1.7). The same range (*d*s = 0.24–1.7) was observed when limiting to the five studies that estimated effect-size against a comparator [23, 24, 26, 27, 28]; all these effects were estimated relative to a usual care condition, in a randomised-controlled trial design, although the nature of 'usual care' likely differs across populations and between individual studies.

Considering findings by population, there was at least one favourable finding for each study population. Behavioural activation treatment was favoured in three of four dementia-focussed studies (observed *d*s 0.9–1.7 [at first follow-up]) and two of three stroke-focussed studies (largest observed *d*s 0.24–1.17), with favourable findings in each of the (single) studies examining effects for patients with epilepsy (*d* = 0.38), Parkinson's disease (*d* = 0.70), and brain injury (*d* unreported).

In terms of effect-sizes at longer-term follow-ups, four randomised-controlled trials [24, 26, 27, 28] provided estimates of effect-size (comparing behavioural activation with usual care) at 5–6 months: these ranged from negligible (0.05 [27]) to moderate (0.77 [24]) magnitude. Of the four randomised-controlled trials, three further provided estimates of effect-size at 12 months, and these again ranged from negligible (0.10 [27]) to moderate (0.70 [26]) magnitude.

Further to effects on patient outcomes, there were reported benefits of patient-focused behavioural activation on caregivers' depression in two studies [23, 32] (reduced caregiver

depression on the Hamilton Depression Rating Scale). Another study [24] found no significant effects of patient-focussed behavioural activation on caregiver strain or leisure activities – although caregivers expressed high satisfaction with the care provided.

In terms of content (aim ii), behavioural activation interventions included the use of psychoeducation, identifying pleasurable activities, scheduling pleasant activities, graded task assignments, and problem-solving. The interventions were delivered by study therapists, care home staff, master's degree students, and unpaid caregivers. In one study, behavioural activation was delivered in two formats (face-to-face and telephone) and was compared to usual care [27], however, due to low recruitment numbers and being under-powered the interventions arms were combined and compared to usual care. Across studies, the number of sessions delivered ranged from one [29] to twenty [24], with most studies delivering between six and nine sessions [23-28, 30, 32]. Where reported, the duration of sessions ranged from 10 minutes [27, 30] to one hour [23, 24, 32]. The duration of the intervention in most studies was one hour. One study used a single session followed by eight weeks of daily text messages [29].

With respect to aim (iii), few adaptations were made to the content of the delivered behavioural activation intervention. Where adaptations were made, the most frequent addition to the programme was problem-solving [25-28]. In one study the problem-solving content was focused on the behavioural challenges, presented by patients with dementia, whereas one study used problem-solving to support access to pleasant activities [25].

Carers were involved in four studies. For instance, psychoeducation was delivered to the caregiver rather than the patient [23, 32], or caregivers (paid and unpaid) assisted in the delivery of behavioural activation [23, 25, 31, 32] or to support access to pleasant activities [25, 31]. Where caregivers were used to deliver behavioural activation, reduction in low mood for

patients was shown in two studies[23, 32], but mixed results were found in relation to reduction in patient depression when paid caregivers supported access to pleasant activities.

Finally, the method of delivery in all studies was one-to-one, and no group studies were identified. In one study [32] both the caregivers and patient attended sessions, with the first three sessions attended by both parties, and the remaining five sessions only the caregivers attended. In all but two studies[26, 30], sessions were delivered face-to-face. However, one study used a single face-to-face session followed by a series of text messages; the content of the messages having been agreed during the initial session [29]. In one study [27], one treatment arm received telephone contact, however, the results were combined with the face-to-face arm and compared to usual care.

Discussion

Overall, we found some indication that behavioural activation is effective in the treatment of depression in individuals with neurological conditions with effects maintained beyond a six-month period. Behavioural activation had a varied effect between small and large in the studies where effect size could be calculated (d= 0.24-1.7, in six of seven randomised-controlled trials) in reducing depression. The largest effect size includes the combined reporting of the intervention arms of behavioural therapy pleasant events and behavioural therapy problem solving [23], when excluding the combined intervention arms the same varied range of small to large effect sizes were observed across included articles. This finding is consistent with a previous meta-analysis, which concluded that behavioural activation for depression in individuals *without* a neurological condition is effective (d = 0.87)[13]. In our review, participants with Parkinson's disease or epilepsy benefitted the most on depression, quality of life, and apathy outcomes. In studies with dementia or stroke samples, varying levels of effectiveness were found. However, these results should be treated with caution, because the quality of some studies was not optimal.

Most studies reported statistically significant differences in the reduction of depression, but effect sizes were not reported in all cases. The variance in the reported outcomes may be a result of the design and delivery of the intervention, clinical condition, outcome measures, timing of assessments, and comparators (or lack thereof). The good quality studies suggested that behavioural activation was clinically and cost effective, and they were reported in a way that would enable replication. The findings from the other studies, however, must be treated with caution because depression was not always the primary presenting difficulty. Furthermore, studies had small sample sizes. Only five of ten studies conducted a sample size calculation or power analysis [24, 26-28, 30], and three studies did not reach their recruitment target [24, 26, 27].

Half of the trials included follow-ups of six-months or longer [23, 24, 26-28]. This is beneficial as it provides an insight into continued benefits of the intervention. All but one [27] - which had no significant benefits in depression outcomes at the end of treatment - reported significant continued benefits at long-term follow-up.

Few studies reported making any adaptations to the intervention specifically for the populations studied. Where adaptations were mentioned, these included adding a problem-solving component to the behavioural activation intervention, delivering sessions by telephone, and teaching caregivers (paid and unpaid) to facilitate behavioural activation and provide access to pleasurable activities.

One study added a problem-solving component to standard behavioural activation, but it was unclear whether this additional component was specific to overcoming barriers to activities or providing support for individuals' difficulties in day-to-day tasks. A more generic problem-solving approach may have introduced a deviation from behavioural therapy interventions. A lack of fidelity assessment and assessment of participant adherence makes it difficult to determine what the participants actually received in terms of 'content' and the

329 ‘dose’ of the intervention. Where reported, the average number of pleasant activities
330 completed increased significantly ($p< 0.005$) from baseline, and a significant positive
331 relationship between depressed mood and duration and frequency of pleasant events was
332 identified (mean = 0.72, $SD = 0.16$, $t(3) = 2.07$, $p<0.08$).
333 In terms of intervention delivery format, we were not able to determine the relative
334 effectiveness of telephone versus face-to-face delivery, as only one study made this
335 comparison, and the outcomes did not differ significantly from each other, however, data
336 were not presented detailing the comparison. Two studies reported a medium effect size in
337 the reduction of depression using a combination of face-to-face and telephone (d=0.70),
338 which suggests that telephone as a mode of delivery may be of benefit to individuals,
339 particularly because some may experience physical difficulties and may struggle to attend
340 appointments. Behavioural activation sessions varied in number and length of sessions. In
341 clinical settings the variability may support clinicians and services with limited resources.
342 However, more research is needed to investigate the effectiveness of behavioural activation
343 in fewer sessions.
344 Using unpaid caregivers to support the delivery of behavioural activation may be a
345 benefit to both the person with a neurological condition and the caregiver themselves.
346 Caregivers experienced a reduction in depression, but behavioural activation had no impact
347 on perceived strain/burden. This may be because the person they care for continues to have
348 care needs, with or without the presence of depression, which the caregiver continues to
349 facilitate. Indeed, high care need is associated with higher levels of caregiver strain and
350 poorer quality of life [40].
351
352 One strength of this review is that the search strategy was tested, and the search terms
353 were refined with a specialist study librarian before the final search, which increased the

likelihood of identifying papers. The electronic search and hand search of full-text reference lists increases confidence that most relevant research was included in this systematic review and that the conclusions made in the review are based on a synthesis of available evidence.

Our findings, however, must be viewed in light of the review's limitations. We could only find a small number of studies to include, and many of the studies had small sample sizes, and considered few neurological conditions. None of the studies compared behavioural activation with another psychological or pharmacological intervention, therefore no direct comparisons of effectiveness were possible. Only peer-reviewed literature was included and as a result the exclusion of unpublished findings may bias the results to demonstrate a positive effect of the intervention. This exclusion criterion was applied to ensure that only methodological robust studies were included. When considering the potential of publication bias, future reviews might benefit from including grey-literature. Finally, only one author screened articles for inclusion.

Future research should consider and address methodological and conceptual limitations of published studies as highlighted in this review. For example, data should be reported for each arm of randomised-controlled trials. Studies should assess the fidelity of the delivery of the behavioural activation intervention, and activity participation should be recorded as an outcome to determine whether changes are directly related to behavioural activation. A fully powered randomised-controlled trial with longer-term follow-ups, and head-to-head comparisons with alternative psychological therapies, with an evaluation of the cost-effectiveness, to determine which is most effective intervention is warranted.

Clinical messages

- There is some evidence that behavioural activation is beneficial in reducing depressive symptoms in several neurological conditions, although the low quality of studies means the findings should be interpreted with caution.
- Behavioural activation interventions have been delivered in a number of formats such as telephone, face-to-face, and carer supported, with varying number and length of sessions.

Acknowledgements

We would like to thank Dr. Danielle DeBoos for her constructive feedback in regard to the focus and concept of the review during its design.

Contribution statement

All authors contributed to the design, completion and writing of the manuscript. All authors reviewed the final draft.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. Lloyd L. Oates carried out this work in part fulfilment of the requirements of his Doctorate in Clinical Psychology at the University of Lincoln and the University of Nottingham.

Funding

This study was part funded by a grant by Health Education East Midlands, UK.

References

1. Kings Fund. Long-term Conditions and Mental Health: the Cost of Comorbidities. London: Kings Fund, 2012.
2. Kanter JW, Baruch DE and Gaynor ST. Acceptance and commitment therapy and behavioral activation for the treatment of depression: Description and comparison. *The Behavior Analyst* 2006; 29: 161-185.
3. Hakim EA, Bakheit AMO, Bryant TN, et al. The social impact of multiple sclerosis - a study of 305 patients and their relatives. *Disability and Rehabilitation* 2000; 22: 288-293. DOI: 10.1080/096382800296755.
4. Motl RW, McAuley E, Snook EM, et al. Physical activity and quality of life in multiple sclerosis: intermediary roles of disability, fatigue, mood, pain, self-efficacy and social support. *Psychology, health & medicine* 2009; 14: 111-124.
5. National Collaborating Centre for Mental Health and National Institute for Health Clinical Excellence. *Depression in adults with a chronic physical health problem: treatment and management*. London: British Psychological Society and the Royal College of Psychiatrists, 2010.
6. Hind D, O'Cathain A, Cooper CL, et al. The acceptability of computerised cognitive behavioural therapy for the treatment of depression in people with chronic physical disease: a qualitative study of people with multiple sclerosis. *Psychology and Health* 2010; 25: 699-712.
7. Hind D, Cotter J, Thake A, et al. Cognitive behavioural therapy for the treatment of depression in people with multiple sclerosis: a systematic review and meta-analysis. *BMC psychiatry* 2014; 14: 5.
8. Cully JA, Paukert A, Falco J, et al. Cognitive-Behavioral Therapy: Innovations for Cardiopulmonary Patients With Depression and Anxiety. *Cognitive and Behavioral Practice* 2009; 16: 394-407. DOI: 10.1016/j.cbpra.2009.04.004.
9. Veale D. Behavioural activation for depression. *Advances in Psychiatric Treatment* 2008; 14: 29-36.
10. Lejuez C, Hopko DR, Acierno R, et al. Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. *Behavior modification* 2011; 35: 111-161.
11. Jacobson NS, Dobson KS, Truax PA, et al. A component analysis of cognitive-behavioral treatment for depression. *Journal of Consulting and Clinical Psychology* 1996; 64: 295-304. 1996/04/01.
12. Dimidjian S, Hollon SD, Dobson KS, et al. Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. *Journal of consulting and clinical psychology* 2006; 74: 658.
13. Cuijpers P, Van Straten A and Warmerdam L. Behavioral activation treatments of depression: A meta-analysis. *Clinical psychology review* 2007; 27: 318-326.
14. Richards DA, Ekers D, McMillan D, et al. Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. *The Lancet* 2016; 388: 871-880. DOI: 10.1016/S0140-6736(16)31140-0.
15. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic reviews* 2015; 4: 1.
16. Gurwitz JH, Sykora K, Mamdani M, et al. Reader's guide to critical appraisal of cohort studies: 1. Role and design. *BMJ: British Medical Journal* 2005; 330: 895.

17. Mamdani M, Sykora K, Li P, et al. Reader's guide to critical appraisal of cohort studies: 2. Assessing potential for confounding. *BMJ: British Medical Journal* 2005; 330: 960.
18. Normand S-LT, Sykora K, Li P, et al. Readers guide to critical appraisal of cohort studies: 3. Analytical strategies to reduce confounding. *Bmj* 2005; 330: 1021-1023.
19. Critical Appraisal Skills Programme. CASP Randomised Controlled Trial Checklist., https://casp-uk.net/wp-content/uploads/2018/01/CASP-Randomised-Controlled-Trial-Checklist.pdf (2018, accessed 25th June 2018).
20. Critical Appraisal Skills Programme. CASP Cohort Study Checklist, https://casp-uk.net/wp-content/uploads/2018/03/CASP-Cohort-Study-Checklist-Download.pdf (2018, accessed 25th June 2018).
21. Critical Appraisal Skills Programme. CASP Qualitative Checklist, https://casp-uk.net/wp-content/uploads/2018/03/CASP-Qualitative-Checklist-Download.pdf (2018, accessed 25th June 2018).
22. Pluye P, Robert E, Cargo M, et al. Mixed methods appraisal tool (MMAT) version 2011. *Proposal: A mixed methods appraisal tool for systematic mixed studies reviews, McGill University, Department of Family Medicine* 2011.
23. Teri L, Logsdon RG, Uomoto J, et al. Behavioral treatment of depression in dementia patients: a controlled clinical trial. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences* 1997; 52: P159-P166.
24. Thomas SA, Walker MF, Macniven JA, et al. Communication and Low Mood (CALM): a randomized controlled trial of behavioural therapy for stroke patients with aphasia. *Clinical rehabilitation* 2013; 27: 398-408.
25. Travers C. Increasing enjoyable activities to treat depression in nursing home residents with dementia: A pilot study. *Dementia* 2017; 16: 204-218.
26. Ciechanowski P, Chaytor N, Miller J, et al. PEARLS depression treatment for individuals with epilepsy: a randomized controlled trial. *Epilepsy & Behavior* 2010; 19: 225-231.
27. Kirkness CJ, Cain KC, Becker KJ, et al. Randomized trial of telephone versus in-person delivery of a brief psychosocial intervention in post-stroke depression. *BMC research notes* 2017; 10: 500.
28. Mitchell PH, Veith RC, Becker KJ, et al. Brief psychosocial–behavioral intervention with antidepressant reduces poststroke depression significantly more than usual care with antidepressant: living well with stroke: randomized, controlled trial. *Stroke* 2009; 40: 3073-3078.
29. Hart T, Vaccaro M, Collier G, et al. Promoting mental health in traumatic brain injury using single-session Behavioural Activation and SMS messaging: A randomized controlled trial. *Neuropsychol Rehabil* 2019: 1-20. 2019/03/15. DOI: 10.1080/09602011.2019.1592761.
30. Butterfield LC, Cimino CR, Salazar R, et al. The Parkinson's Active Living (PAL) Program: a behavioral intervention targeting apathy in Parkinson's disease. *Journal of geriatric psychiatry and neurology* 2017; 30: 11-25.
31. Feliciano L, Steers ME, Elite-Marcandonatou A, et al. Applications of preference assessment procedures in depression and agitation management in elders with dementia. *Clinical gerontologist* 2009; 32: 239-259.
32. Teri L and Uomoto JM. Reducing excess disability in dementia patients: Training caregivers to manage patient depression. *Clinical Gerontologist* 1991; 10: 49-63.
33. Smith JD. Single-case experimental designs: a systematic review of published research and current standards. *Psychological Methods* 2012; 17: 510-550. 2012/08/01. DOI: 10.1037/a0029312.

34. Alexopoulos GS, Abrams RC, Young RC, et al. Cornell scale for depression in dementia. *Biological psychiatry* 1988; 23: 271-284.
35. Hamilton M. A rating scale for depression. *Journal of neurology, neurosurgery, and psychiatry* 1960; 23: 56.
36. Lincoln N, Sutcliffe L and Unsworth G. Validation of the Stroke Aphasic Depression Questionnaire (SADQ) for use with patients in hospital. *Clin Neuropsychol Assess* 2000; 1: 88-96.
37. Yesavage JA, Brink TL, Rose TL, et al. Development and validation of a geriatric depression screening scale: a preliminary report. *Journal of psychiatric research* 1982; 17: 37-49. 1982/01/01.
38. Kroenke K, Spitzer RL and Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001; 16: 606-613. 2001/09/15. DOI: 10.1046/j.1525-1497.2001.016009606.x.
39. Derogatis LR, Lipman RS, Rickels K, et al. The Hopkins Symptom Checklist (HSCL): A self-report symptom inventory. *Behavioral science* 1974; 19: 1-15.
40. Hand A, Oates LL, Gray WK, et al. The role and profile of the informal carer in meeting the needs of people with advancing Parkinson's disease. *Aging & mental health* 2017: 1-8.

Journal Paper

Authors and affiliations, byline, and author note to add following masked review

Lloyd L. Oates[1,2], Nima Moghaddam[1], Christopher Meek[3], Nikos Evangelou[4], & Roshan das Nair[5]

1. Trent Doctorate in Clinical Psychology, University of Lincoln

2. Lincolnshire Partnership NHS Foundation Trust

3. Trent Doctorate in Clinical Psychology, University of Nottingham

4. Division of Neurosciences, Nottingham University Hospitals NHS Trust

5. Institute of Mental Health, University of Nottingham

Author Note

This study was part funded by a grant by Health Education East Midlands. Lloyd L. Oates carried out this work in part fulfilment of the requirements of his Doctorate in Clinical Psychology at the University of Lincoln and the University of Nottingham. All authors contributed to and reviewed the final draft.

Correspondence to: Professor Roshan das Nair, Professor of Clinical Psychology & Neuropsychology, B19, Institute of Mental Health, Jubilee Campus, University of Nottingham, Nottingham, NG7 2TU, UK.

Email: Roshan.Dasnair@nottingham.ac.uk

Behavioural Activation for Low mood in Multiple Sclerosis: Single-case experimental design

(Authors and byline to be added after masked review, as in cover letter)

Abstract

Purpose: People with secondary progressive multiple sclerosis (MS) experience high rates of depression. Behavioural activation may represent an accessible therapeutic intervention for this group. We aimed to: (a) examine preliminary evidence of efficacy of a behavioural activation intervention, for people with secondary progressive MS experiencing low mood; (b) understand the feasibility; (c) examine impact on mood, fatigue, and quality of life (QoL); and (d) understand participants' experience of the intervention.

Research Method/Design: A mixed-method multiple single-case experimental design was used to investigate the effectiveness of a five-session behavioural activation intervention. Depression was measured using the Hospital Anxiety and Depression Scale. Data were analysed using visual analysis and reliable and clinically significant change analysis. Post-intervention change interviews were completed and analysed using framework analysis.

Results: Eight people were recruited, of which six established a stable baseline and proceeded to intervention. Five participants completed intervention and change interviews. Systematic reduction in depression was observed in three of five completers and reliable and clinically significant reduction was observed in two of these three participants. Participants reported benefits from the intervention and that it was acceptable, even in the face of competing demands. No changes were reported in fatigue or physical health related QoL. Two participants reported reliable improvement for mental health related QoL.

Conclusion: There was some evidence to suggest behavioural activation led to a reduction in depressive symptoms when engagement in positively reinforcing behaviour

increased. No changes in fatigue were reported suggesting engagement in behavioural activation does not negatively affect fatigue.

Trial registration: ClinicalTrials.gov Identifier NCT03935529

*Key words***:** Depression, Behavioural Activation, Secondary Progressive Multiple Sclerosis, Behavioural Therapy, Activity Scheduling

Impact

- Identifying accessible psychological interventions in those with long-term neurological problems is important. This study provides early support for the use of behavioural activation for people with depression and secondary progressive multiple sclerosis.
- Behavioural activation is an acceptable intervention for people with secondary progressive multiple sclerosis, which reduces low mood when engagement in positive reinforcement occurs.
- Despite increasing activities to engage in positive reinforcement there were no adverse effects to individuals' mental or physical health.

Introduction

Multiple Sclerosis (MS) is a neurodegenerative disease and one of the most prevalent neurological conditions affecting young adults (Confavreux & Vukusic, 2006),[1] with a mean age of onset of 30 years (Rejdak et al., 2010). Initially, the disease has repeated events of symptom presentation before symptoms subside, in a phase known as relapse remitting MS (Confavreux & Vukusic, 2006). Over time, many people with MS find that symptom presentation becomes unremitting, leading neurologists to confirm transition to secondary progressive MS (a stage of MS; Confavreux & Vukusic, 2006). Symptoms then continue to gradually worsen and include increased weakness; difficulties with coordination; muscle stiffness; and troubles with fatigue, depression, and cognition (Compston & Coles, 2008).

[1] See Extended Introduction 1.1 and 1.2 for further details about neurological conditions and multiple sclerosis

Depression in MS

Reported rates of depression in people with MS are high, with a lifetime prevalence of around 50% (Siegert & Abernethy, 2005). These prevalence rates are higher than in the general population and for other conditions, such as stroke (Galeazzi et al., 2005; Patten et al., 2003). In a study exploring point prevalence, depression was reported in 41.8% of participants (Chwastiak et al., 2002). The authors found that people with advanced MS were much more likely to experience clinically significant depression than those with minimal disease symptoms. This was further supported by a large-scale UK-based survey (*n*=4187) demonstrating higher prevalence of depression in those with secondary progressive MS versus other types of MS (Jones et al., 2012).[2]

Factors contributing to depression in people with MS

The high prevalence of depression in MS may result from illness-related challenges, such as the unpredictable nature of the disease which leads to a loss of contact with environmental contingent reinforcement. For example, people with MS report changes in behaviour (e.g., lethargy), and mood (e.g., depression) because of the unpredictability of their condition (Wilkinson & das Nair, 2013). In addition, people with MS report a breakdown in employment, poorer medication adherence, and increased risk of self-harm and suicide, due to their depression (Hind et al., 2014).

Once diagnosed, people with MS often reduce their social and leisure activities, that were known to promote positive mood and wellbeing (Hakim et al., 2000; Motl et al., 2009). Decreased activity can contribute to the development, maintenance, and exacerbation of low mood through loss of contact with contingencies that were previously reinforcing and mood enhancing (Kanter et al., 2006). Due to physical

[2] See Extended Introduction 1.3 for further details about depression

difficulties, people with MS struggle to find new activities that have reinforcing or pleasurable consequences (Motl et al., 2009).

The relationship between functional disability and depression, however, is debated, with some studies reporting a positive relationship between MS-related disability and depression, and others claiming depressive episodes are independent of MS-symptom severity (Chwastiak et al., 2002; Millefiorini et al., 1992).[3]

Interventions for depression in people with multiple sclerosis

In the UK, there are no specific guidelines for the treatment of depression in people with MS. Rather, practitioners are referred to more general guidance for treating depression in chronic physical health problems, which recommend Cognitive Behavioural Therapy (CBT; National Institute for Health and Care Excellence, 2009). CBT is a time-limited psychotherapy which aims to use problem solving strategies, alongside challenging negative thought-patterns through reappraisal, to bring about change in emotions and behaviours (Beck, 1964).[4]

In a review examining the efficacy of CBT for people with MS, seven studies were analysed (Hind et al., 2014). A medium effect-size (standardised mean difference of 0.5) was reported, favouring CBT over standard care for reducing depression in people with MS. However, the authors concluded that further studies should explore duration and modalities of therapy for individuals at differing disease stages. Studies included in this review had small sample sizes in the intervention group (*n*=9-63) and effects were reported for combined patient groups, rather than distinguishing effects for

[3] See Extended Introduction 1.3.3 and 1.3.4 for further details about maintenance of depression and impact

[4] See Extended Introduction 1.4 and 1.5 for further details about interventions

people with secondary progressive MS versus relapsing-remitting MS. Where individual comparisons were made, sample sizes were small ($n \leq 18$).

Indeed, when considering the accessibility of therapy, it is necessary to explore the impact of the client's physical difficulties in relation to psychological interventions. In a recent study examining CBT for people with MS, Ytterberg et al. (2017) reported that CBT therapists can find it difficult to determine whether client-reported symptoms, such as fatigue, are attributable to depression or physical characteristics of MS. In addition, due to cognitive difficulties and problems understanding content, therapy needed to be conducted at a much slower pace.

The effectiveness of computerised-CBT for people with MS has also been investigated (Hind et al., 2010). Participants reported issues with the format, including the burdensomeness of computer-based tasks, increased social isolation, and difficulty setting goals in the absence of human support. Therefore, therapy needs to be adapted and supported by practitioners.

The influence of number and duration of intervention sessions has not been investigated in people with MS. However, there is increasing evidence for the effectiveness of short-term CBT in general. For example, services offering guided self-help for depression, with an average of six, thirty-minute sessions, have seen recovery rates ranging from 44-77% (Gyani et al., 2013). However, reported rates of recovery do not include data for individuals with physical difficulties, nor do they identify data pertaining to people with MS.

Consequently, CBT may not be the most beneficial intervention for people with MS and investigating other therapy types or adaptations, may lead to a helpful alternative. Given the cognitive difficulties people with MS report, therapies that are less cognitively demanding may be more suitable than CBT.

Behavioural activation as a potential intervention for depression in secondary progressive multiple sclerosis

The behavioural theory of depression posits that depression is a result of reduced contact with response-contingent positive reinforcement and inadequate social skill (Lewinsohn, 1974). Using behavioural theory, Lewinsohn et al. (1976) developed a treatment manual for depression known as behavioural activation. Behavioural activation aims to reduce behaviours that maintain or exacerbate depression, by promoting counteracting behaviours (Martell et al., 2001), using strategies such as activity monitoring and scheduling (Jacobson et al., 1996). By using activity strategies, environmental deficits in positive reinforcement and difficulties in obtaining and maintaining reinforcement are addressed (Kanter et al., 2010).

Jacobson et al. (1996) found that the behavioural elements of CBT are as effective as using a combination of behavioural and cognitive interventions. In a study comparing behavioural activation, cognitive therapy, and antidepressant medication in the treatment of adults with depression, behavioural activation was comparable to antidepressant medication and both were significantly more effective than cognitive therapy (Dimidjian et al., 2006). Behavioural activation has also been used with people with other neurological conditions, such as stroke (including those with aphasia; Thomas et al., 2016). As people with secondary progressive MS can experience fatigue and cognitive difficulties, which can complicate engagement, behavioural activation may represent a less burdensome intervention versus CBT.[5]

[5] See Extended Introduction 1.6 for further details about behavioural activation

Behavioural activation and values

Although behavioural activation may be less burdensome than CBT, individuals can have difficulties identifying activities as targets for promotion and increased engagement. For example, individuals with depression often select aversive, difficult to complete activities that have delayed reinforcement (Lejuez et al., 2011). To overcome this, some psychological interventions, such as Acceptance and Commitment Therapy (ACT), encourage individuals to modify their behaviour by adhering to their values. Values are defined as verbally constructed global desired life consequences (Hayes et al., 1999). Functionally, values are seen as reinforcing and values identification may orientate an individual toward a defined set of multiple positive reinforcers (Bonow & Follette, 2009). However, ACT is similar to CBT in that – when delivered comprehensively – it contains multiple core components that are cognitively demanding (Hayes et al., 1999) and thus likely to present similar barriers to engagement for an MS population (particularly individuals with advanced symptoms/ secondary progressive MS).

In behavioural activation, the function of values may be used to motivate and sustain behaviours, when reinforcement from the behaviour is not expected to immediately occur (Kanter et al., 2009). This is because values are seen as verbally-derived reinforcement, meaning behaviour may be sustained in the face of competing aversive consequences that can stop behaviour and lead to avoidance (Kanter et al., 2010).

As a result, comprehensive manuals for behavioural activation have been developed (Lejuez et al., 2011), some of which include values-led behaviour. One such manual is the Brief Behavioural Activation Treatment for Depression - Revised (BATD-R; Lejuez et al., 2011). The BATD-R is a ten-session manual for the treatment

of depression (Lejuez et al., 2011). In a randomised-controlled trial, the original manual significantly reduced depression (*d* =.73; Hopko et al., 2003). Further, there is evidence supporting the efficacy of this intervention using varying formats and length (Gawrysiak et al., 2009). Whilst between-group benefits have been demonstrated, less is known about between-person variability in response to the BATD-R, or about the mechanisms that achieve change.

Study rationale

Depression is highly prevalent among people with MS. More specifically, as the disease progresses, people with MS are more likely to develop depression and there is limited evidence in suitable interventions in this group. CBT has demonstrated reduced rates of depression in people with MS. However, there are few studies that investigate the most appropriate duration, delivery modality, or individual adaptations.

Furthermore, less is known about CBT for people with secondary progressive MS. This is problematic, because continued reduction in physical and cognitive ability, combined with greater incidence of depression, may make accessing and engaging in therapies difficult. The need for therapeutic interventions for this group of people is highest, yet existing research is sparse. Behavioural activation may offer an accessible, parsimonious approach.[6]

Aims of Investigation

The aims of the study were to explore:

- the preliminary efficacy of a behavioural activation intervention, for people with secondary progressive MS experiencing low mood.

[6] See Extended Introduction 1.7 for further details about rationale

- the feasibility of recruiting, retaining, and delivering the intervention.
- mechanisms of change in outcomes (where observed) using process measures
- participants' experience of the intervention.

Method

A mixed-methods, multiple single-case experimental design (MSCED) was used.[7] The study was registered on ClinicalTrials.gov (reference NCT03935529). Original data were collected for the purpose of testing the hypotheses in the manuscript.

Ethics

Ethical approval for the study was granted by the East Midlands – Nottingham 2 ethics committee (ref: 19/EM/0013). Informed consent was obtained from each participant by the study researcher (LLO). Participants received a £20 Amazon voucher following the completion of the interview post-intervention.[8]

Participants

Participants were recruited through a neurology outpatient clinic at an acute hospital in Nottingham, UK, and through an advertisement placed in a regional MS Society newsletter. Participants were aged 18-years or over with a verified diagnosis of secondary progressive MS. Participants were English speaking, willing and able to give consent, and had access to and were able to use a telephone and computer. Potential participants were screened for depression using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). Participants were eligible if they scored eight

[7] See Extended Methods 2.1 and 2.2 for further details about epistemology and design
[8] See Extended Methods 2.3 for further details about ethics

or above on the depression subscale, indicating at least mild levels of depression. Participants receiving other psychotherapy were excluded.[9]

Measures

Screening and primary outcome

The HADS was used to screen participants for inclusion and in line with study aims, used to investigate change in depression. High sensitivity and specificity have been reported versus clinical interview and other measures in people with MS (Honarmand & Feinstein, 2009; Nicholl et al., 2001). In a systematic review completed by Hind et al. (2016) comparing mood measures in MS studies the HADS had a sensitivity of 90% which was the highest of all the measures compared. The HADS also had a specificity of 87% which was the third highest of all measures compared. For the purpose of the study, selection based on sensitivity was selected. The measure consists of 14 questions split into two subscales of seven questions (depression and anxiety). Participants rate their responses to statements over the last week from 0 to 3 with higher scores indicating a greater presence of depression or anxiety.[10]

Baseline

The Patient Health Questionnaire 2 (PHQ2; Kroenke et al., 2003) was used to establish a baseline on the outcome of primary interest (depression). The questions were altered from asking ‘over the last week’ to ‘over the last two days’. Higher scores represent greater incidence of low mood.

[9] See Extended Methods 2.4 for further details about participants and recruitment
[10] See Extended Methods 2.5 for further details about measures

Process measures

The Behavioural Activation for Depression Scale Short Form (BADS-SF; Manos et al., 2011) was used to track participant engagement in behavioural activation. The measure consists of nine items on a Likert sale from 0 (not at all) to 6 (completely) and scores range from 0 to 54, with higher scores representing higher activation.

The Engaged Living Scale (ELS; Trompetter et al., 2013) was used to identify alignment to values, to allow us to understand the impact of values-based action. The measure assesses an engaged response style, in response to an individual's values and committed action toward those values. Participants rate 16 statements on a Likert scale from 1 (not at all) to 5 (totally agree). Total scores range between 16 and 80, with higher scores indicating a more engaged response style.

Secondary outcomes

The Modified Fatigue Impact Scale Short Form (MFIS-SF; Vickrey et al., 1995) was used to assess fatigue. The measure consists of five questions on a Likert scale from 0 (not at all) to 4 (almost always) and total scores range from 0 to 20, with higher scores indicating greater fatigue.

Changes to participants' health-related quality of life (QoL), were investigated using the Short Form-12v2 Health Survey (SF-12v2; Ware et al., 1996). The SF-12v2 addresses health concepts from the participant's perspective. The measure has 12 questions and comprises physical and mental health concepts.

Intervention

The BATD-R manual (Lejuez et al., 2011) was adapted for supported self-help from ten sessions to five. The five unique sessions of the manual were used for the sessions. The manual had phrases relating to cancer removed.[11]

Design

A MSCED was used to investigate study aims. Participants received the behavioural activation intervention to investigate changes to mood and whether/how behavioural activation processes accounted for any observed change. As the intervention involved learning, it cannot be unlearned, therefore the effect of the intervention (or component phases) cannot be readily taken away. The study used an AB design, where A was baseline and B was the intervention.

Post-intervention, one-to-one interviews were conducted to inform feasibility aims (acceptability of the intervention and research procedures). The interview schedule was based on the Elliott and Timulak (2005) change interview.

Data collection and assessment

Data were collected online, via participant self-report using Qualtrics (Qualtrics, Provo, UT). A single reminder was sent via the system if participants had not responded within 48-hours. Demographic data included: age, gender, relationship status, care support (paid /unpaid carers, hours per week), ethnicity, education level, and employment status. Clinical data included: diagnosis, and disease duration and progression history.

[11] See Extended Methods 2.6 for further details about design method

Pre-intervention assessments were completed by participants, after obtaining consent, prior to establishing a baseline. The assessments were re-administered at mid-intervention and post-intervention (final session). The assessment battery included: The HADS, ELS, BADS-SF, MFIS-SF, and SF-12v2 Health Survey. In addition to the pre-, mid-, and post-intervention battery, the HADS, ELS, and BADS-SF were administered weekly.

The PHQ2 was administered every-other-day during the baseline phase, to establish a baseline for the primary outcome variable of interest (depression). Questions were adapted to ask 'over the last two days' because no alternative, high frequency, measure exists. Trend scores were plotted to convert to HADS equivalent.

Procedure

Potential participants were provided with study information and were contacted by telephone after one-week to answer questions and to complete screening using the HADS. Those meeting inclusion criteria were recruited. Those not meeting the inclusion criteria were excluded from the study and provided with a leaflet on managing emotions and signposted to seek further support from their GP.

Participants completed the pre-intervention measures. The following day participants received an email with a link to complete the measures, using Qualtrics, to establish a baseline. Participants received an email every-other-day to complete baseline measures.

A baseline for each participant was established over two weeks in which no other contact or procedure was introduced. The baseline was considered stable (established) when the participant had recorded no less than three data points on the PHQ2 that showed no trend toward improvement. If stability had not been

demonstrated, the baseline was extended on a week-by-week basis, for a maximum of two weeks. If a stable baseline had not been established by the fourth week, the participant exited the study and was provided with information about managing distress and accessing further support.

For participants with an established baseline the intervention was introduced. Participants received five sessions with an optional troubleshooting session. All sessions were delivered by LLO (a trainee clinical psychologist, working under the supervision of two qualified clinical psychologists) and audio recorded. The first session took place at the participant's home and lasted up to two hours; all further sessions used Skype or telephone depending on the participant's preference. Sessions three, four, and five were fortnightly, with the optional session between session three and four. Following the fifth session participants received a treatment evaluation session to review the homework tasks from session five.

Post-intervention

Participants completed a 30-minute, one-to-one, audio recorded phone interview conducted by CM (another trainee clinical psychologist, with experience of conducting interviews) who had not been involved in the study design or analysis.[12]

Analysis

Single-case experimental design

Visual analysis was used to identify any phase-related changes in process and outcome variables. Time-series data from the HADS depression subscale and BADS-SF were graphed and inspected visually for phase related change (see Figures 2 and 3).

[12] See Extended Methods 2.7 for further details about intervention/procedure

341 The analysis provided a visual representation of the covariation between
342 process and outcome measures, to explore whether and how the intervention had an
343 impact on mood and activation. Conservative dual-criterion (Fisher et al., 2003) and
344 percentage exceeding the median (Ma, 2006) were used. Conservative dual-criterion
345 analysis was used as the primary analysis. Conservative dual-criterion analysis
346 extrapolates baseline mean and trend lines through the intervention-phase, to enable
347 identification of intervention-phase datapoints that are indicative of positive change
348 (i.e., those 'exceeding' baseline level and trend, in the direction of improvement).
349 Conservative dual-criterion was used to account for any potential trend in baseline when
350 PHQ2 scores were converted to HADS scores.[13] Percentage exceeding the median
351 analysis explores how many intervention-phase data points exceed the baseline median
352 in the direction of improvement, and provides an effect size (highly effective treatment
353 ≥.9, moderately effective treatment .7-.9, and questionable or non-effective treatment
354 <.7). Reliable and clinically significant change indices were used to provide quantitative
355 decision criteria for identifying the statistical robustness, and practical importance, of
356 visually apparent shifts over time.[14]
357
358 ***Interviews***
359 Framework analysis (Gale et al., 2013) of telephone interviews was used to
360 explore participants' experience and to assess feasibility. The analysis was conducted
361 by LLO. Predefined codes regarding the feasibility of the study were assigned to the
362 data and summarised into a feasibility framework.
363

[13] See Extended Methods 2.8.2.2 for baseline establishment
[14] See Extended Methods 2.8 for further details about analysis

Intervention fidelity

Audio recordings of the intervention sessions were evaluated by NM. Fidelity was investigated using a set framework, to investigate content delivery adherence.[15]

Results

The study ran from July 2019 to March 2020. In total 11 individuals were screened, and eight participants were recruited. Baseline stability was established for six participants. Of the six participants, one participant withdrew from the study after the second intervention session. Sessions ranged from 38 minutes to 120 minutes. There were no missed sessions. Participant demographics of those who established a baseline can be seen in Table 3.[16]

Table 3

Participant demographics of those who established a baseline

Demographic	PS01	PS02	PS03	PS04	PS05	PS06
Age (years)	66	56	60	64	51	73
Gender	Male	Male	Female	Male	Female	Male
Relationship	Divorced	Married	Widow	Widower	Married	Married
Care status	Paid (15hr)	Unpaid	None	Paid (5 hours)	Unpaid (<4)	Unpaid (42 hours)
Education	University	Sixth form	College	University	School	School
Employment	Retired	Retired	Retired	Retired	Unemployed	Retired
Diagnosis duration	29 years	20 years	38 years	12 years	27 years	16 years
SPMS duration	10 years	3 years	19 years	12 years	3 years	3 years

Note. All participants were of white British ethnicity.
[a] SPMS, Secondary progressive multiple sclerosis

[15] See Extended Methods 2.8 for further details about analysis
[16] See Extended Results 3.1-3.5 for further details about results: demographics, feasibility, attrition, sessions, and baseline data

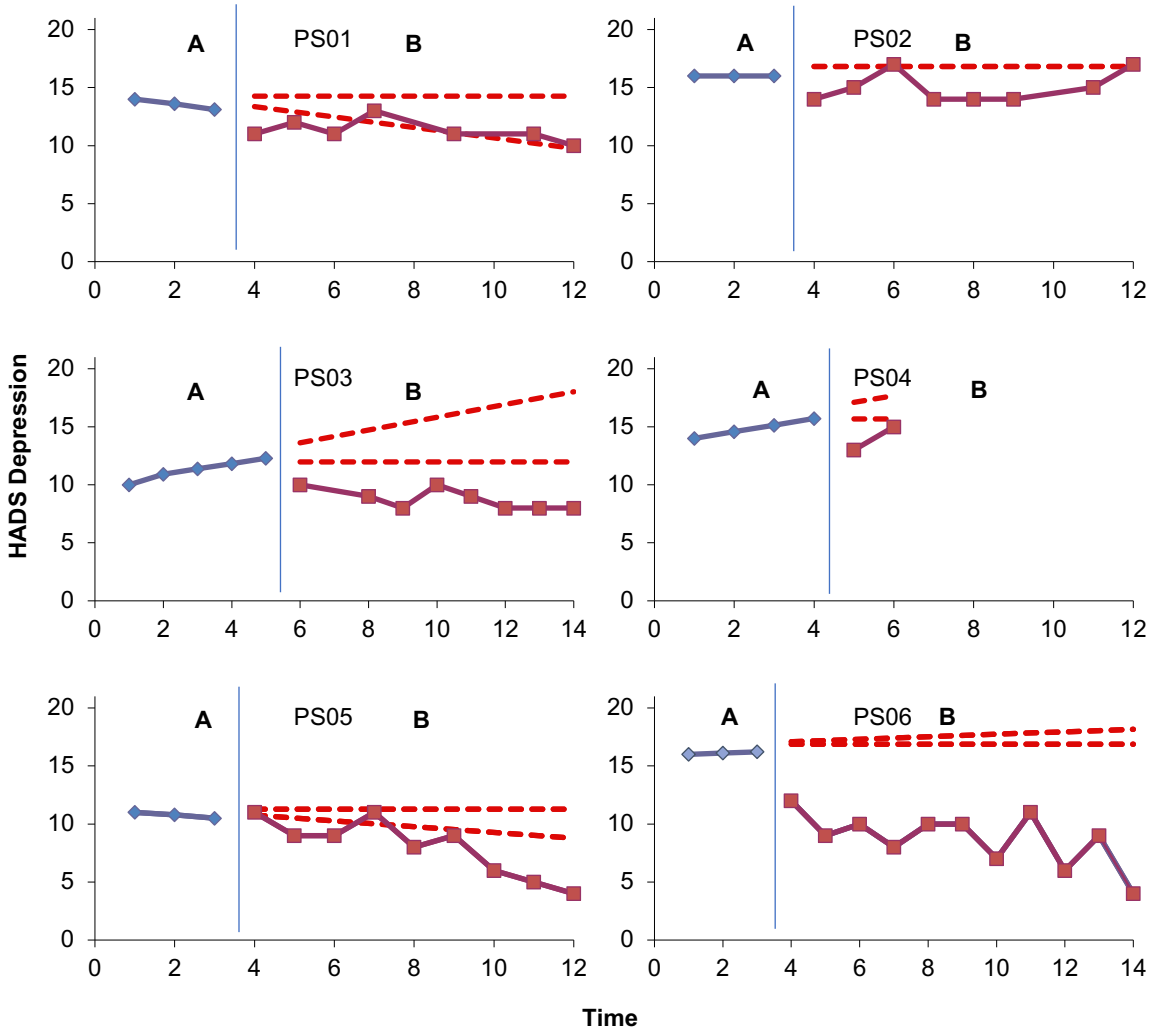
Visual Analysis of Change

HADS Depression

Changes in depression can be seen in Figure 2.

Figure 2

Depression scores for each participant throughout baseline and intervention



Note. This figure demonstrates participants' weekly depression scores from baseline to the end of intervention. Higher scores on the Hospital Anxiety and Depression Scale (HADS) – depression subscale indicate greater presence of depression, possible maximum of 21 and minimum of 0. The clinical cut off is 8.

[a] *Baseline phase is denoted by section A. Intervention phase is denoted by B. A vertical line is presented to distinguish between phases.*

[b] *Dashed lines in phase B represent mean baseline score plus .25 Standard Deviation and projected trend from baseline scores.*

[c] *Time on the x axis is equivalent to one week.*

401 *[d] The first baseline score is the participant's HADS – depression subscale score. The*
402 *following baseline scores were converted from the Patient Health Questionnaire 2 trend*
403 *to HADS- depression subscale equivalent*
404 *[e] PS06 had additional weekly measures due to requesting no sessions over the Christmas*
405 *break time point nine and ten.*
406

407 Overall, depression appeared to reduce across phases in three of five participants
408 (PS03, 05, & 06). There were sufficient data points below mean and trend lines to
409 conclude systematic change occurred from baseline to treatment in two of five
410 participants (PS03 & 06). At the end of intervention, two participants (PS02 & 05) were
411 one observation point on the HADS from recording the necessary number of
412 observations below mean and trend lines to demonstrate systematic change. Generally,
413 gains appeared to show gradual improvement, except for PS02, where there was no
414 change. When assessing percentage exceeding the median, three of five participants
415 (PS01, 03, & 06) demonstrated highly effective treatment (≥.9) and two participants
416 (PS02 & 05) demonstrated moderately effective treatment (0.7-0.9). Reliable and
417 clinically significant change was observed from baseline to end of intervention in two
418 participants (PS05 & 06). Of note, participant 03 was at cut off (8) for the final session.
419 Participant pre-, mid-, and intervention scores can be seen in Table 4.[17]
420
421

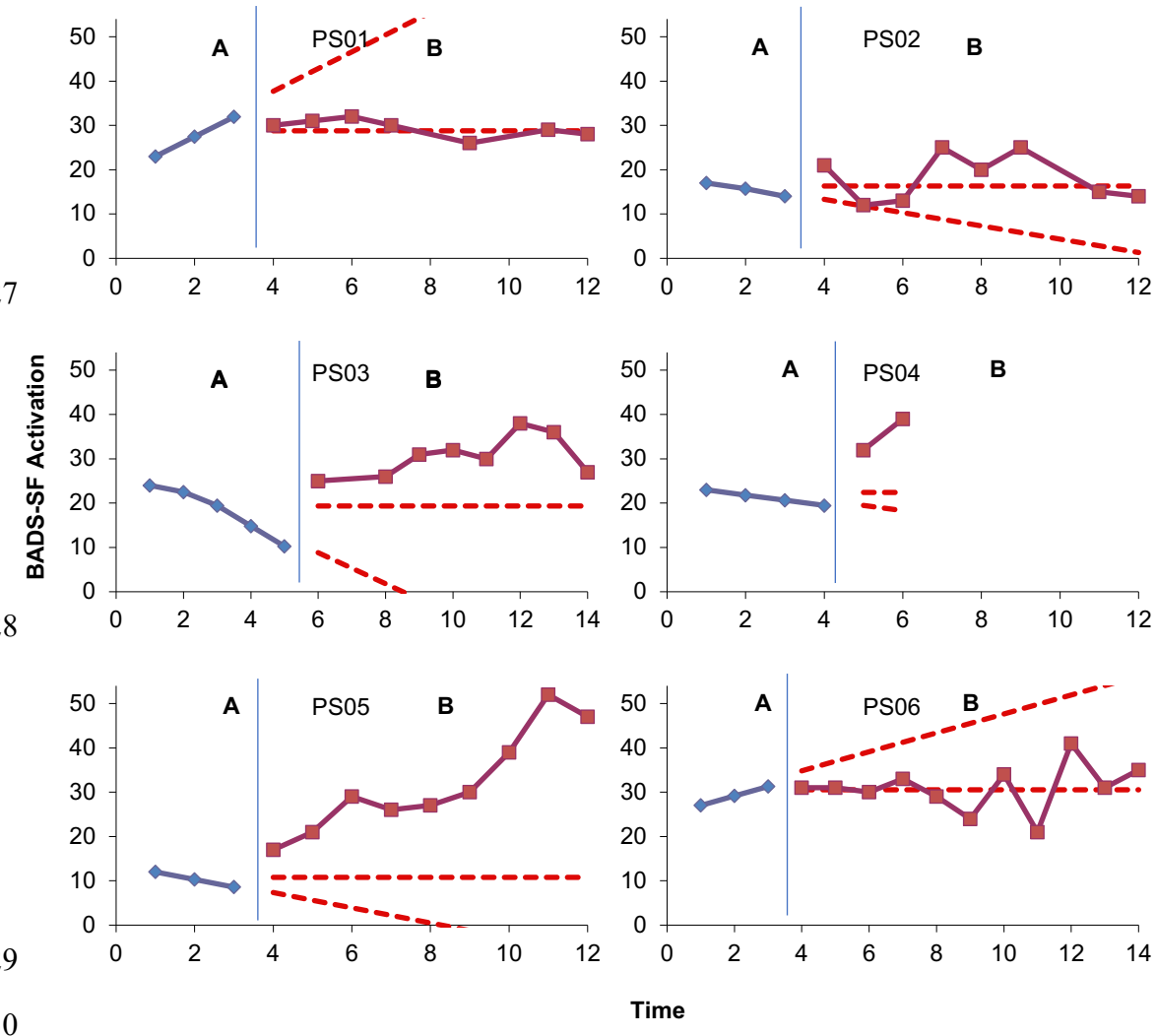
[17] See Extended Results 3.4 for further details about baseline establishment and conversion

BADS Activation

Changes in activation can be seen in Figure 3.

Figure 3

Activation scores for each participant throughout baseline and intervention



Note. This figure demonstrates participants' weekly activation scores from baseline to the end of intervention using the Behavioural Activation for Depression Scale – Short Form (BADS-SF). Higher scores on the BADS-SF indicate greater engagement in activities, possible maximum of 54 and minimum of 0.

[a] Baseline phase is denoted by section A. Intervention phase is denoted by B. A vertical line is presented to distinguish between phases.

[b] Dashed lines in phase B represent mean baseline score plus .25 Standard Deviation and projected trend from baseline scores.

[c] Time on the x axis is equivalent to one week.

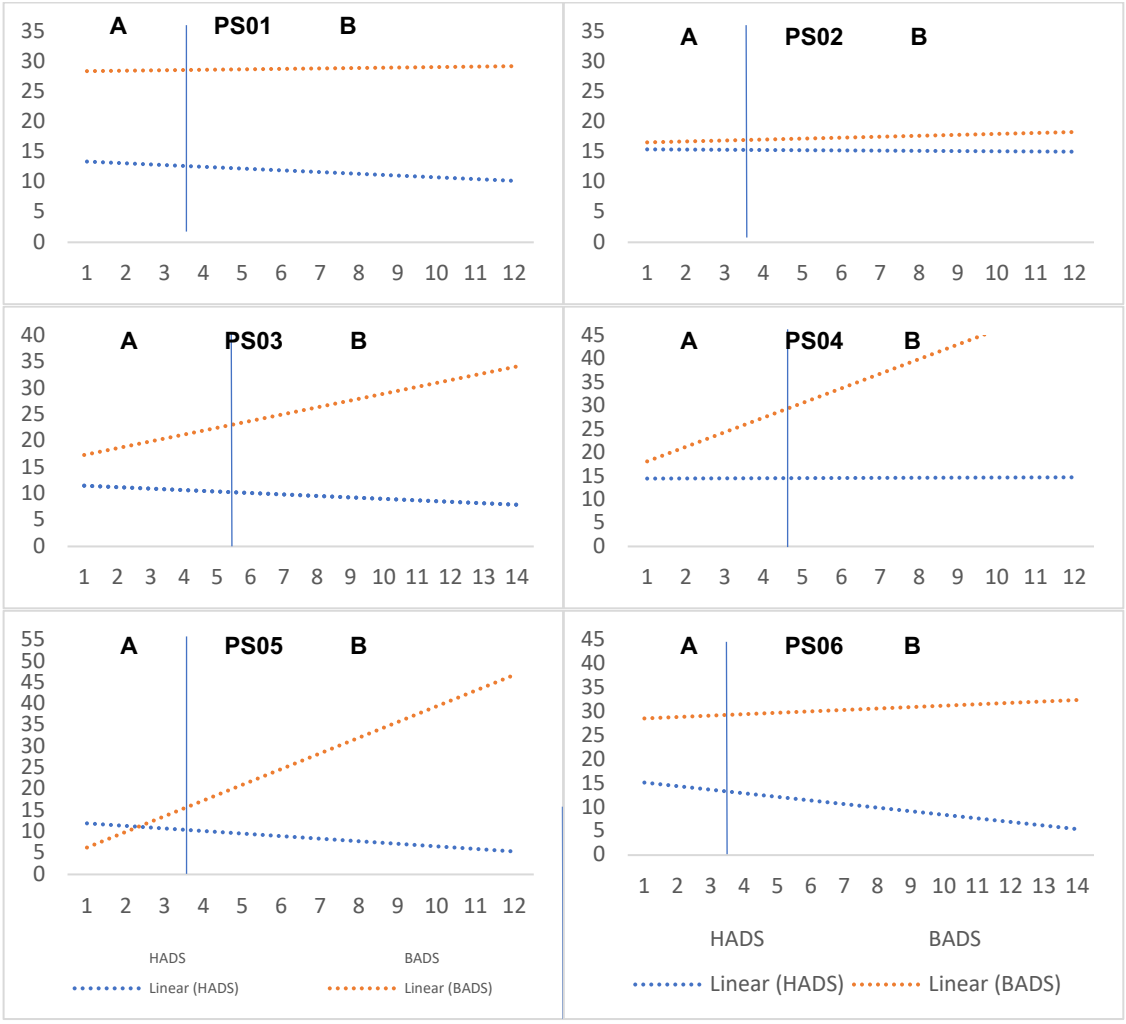
[d] PS06 had additional weekly measures due to requesting no sessions over the Christmas break time point nine and ten.

Overall, activation scores appeared to covary with depression scores: such that participants demonstrating systematic change in one tended to demonstrate systematic change in the other (and vice-versa) – providing some evidence for theoretically-congruent process-outcome mapping. However, PS06 was an exception. PS06 demonstrated a clear change in depression but (partly owing to baseline trend) not in activation.

Where systematic changes did not occur on the HADS, the scores on the BADS-SF were similar, Covariation between depression and activation can be seen in Figure 4. There were sufficient data points above mean and trend lines to conclude systematic change occurred from baseline to treatment in two of five participants (PS03 & 05). Gains appeared to show gradual improvement. Whilst systematic change was not observed on the HADS for participant 05, the systematic change in activation scores coincides with reliable and clinically significant improvement. Participant 06 did not demonstrate systematic improvement in activation from expected observations using baseline data, however, baseline activation levels were increasing which coincides with the observed systematic reduction in depression scores. When assessing percentage exceeding the median, two of five participants (PS03 & 05) demonstrated highly effective treatment (≥.9), two participants (PS01 & 06) demonstrated moderately effective treatment (0.7-0.9). Reliable change was observed in one participant (PS05), but clinically significant change was not.

Figure 4

Covariation of depression and activation scores for each participant throughout baseline and intervention



Note. This figure demonstrates participants' weekly depression and activation scores from baseline to the end of intervention using the Hospital Anxiety and Depression – depression subscale (HADS) and the Behavioural Activation for Depression Scale – Short Form (BADS-SF). Higher scores on HADS indicate greater presence of depression, possible maximum of 21 and minimum of 0. The clinical cut off is 8. Higher scores on the BADS-SF indicate greater engagement in activities, possible maximum of 54 and minimum of 0.

[a] Baseline phase is denoted by section A. Intervention phase is denoted by B. A vertical line is presented to distinguish between phases.

[b] Dashed lines show the linear trend throughout the study.

[c] Time on the x axis is equivalent to one week.

[d] PS06 had additional weekly measures due to requesting no sessions over the Christmas break time point nine and ten.

Engaged living

Overall, weekly observations of engaged living varied amongst participants, but increased engaged living corresponded with changes in reduction of depression and increase in activation in two of three participants (PS05 & 06), no changes were observed in two participants which coincided with no change in depression (PS01 & 02). Reliable and clinically significant change was observed in two participants (PS05 & 06), however, reliable deterioration was observed in one participant (PS03). A comparison of engaged living scores can be seen in Table 4. At observation seven, participant 02 scored their highest engaged living score which demonstrated reliable improvement from baseline before they had a relapse in symptoms. Participant 04 scored within non-clinical cut off pre-intervention (50) and at final data collection was still within non-clinical cut off (57).[18]

Fatigue

Fatigue was recorded pre-intervention, at mid-point, and post-intervention. Reliable and clinically significant change was not observed in any participants. A comparison of fatigue scores can be seen in Table 4. Fatigue did not increase for any participant from pre-intervention to post-intervention. Participant 04's fatigue score pre-intervention was 5 and no further data were collected as they withdrew from the study.[19]

Quality of life

Scores on the SF-12v2 failed to meet clinically significant change in all participants. However, two participants demonstrated reliable improvement on the

[18] See Extended Results 3.6 for further details on Engaged Living Scale and subscales
[19] See Extended Results 3.7 for further details on Modified Fatigue Impact Scale

Mental Component Scale (MCS). No reliable change was observed on the Physical Component Scale (PCS). Further, no participants showed reliable deterioration on the MSC or the PCS. Comparison of scores is shown in Table 4. Participant 04's pre-intervention scores were 38.22 on the MCS and 44.22 on the PCS.

Table 4

Participant scores on measures pre-, mid-, and post-intervention and reliable and clinically significant change criteria

Participant	Outcome measure	Cut off	RC min	Pre-intervention	Mid-intervention	Post-intervention
PS01	HADS-DS	<8	4.94 (↓)	14	13	10
	BADS-SF	>9.26	9.65 (↑)	23	30	18
	ELS	>45.14	6.86 (↑)	53	52	49
	MFIS-SF	<2.82	5.98 (↓)	15	18	12
	SF12v2 PCS	>60.04	12.50 (↑)	31.98	25.96	28.21
	SF12v2 MCS	>65.54	11.76 (↑)	48	32.96$^{\pm}$	43.05
PS02	HADS-DS	<8	4.94 (↓)	16	14	17
	BADS-SF	>9.26	9.65 (↑)	17	20	14
	ELS	>45.14	6.86 (↑)	19	18	16
	MFIS-SF	<2.82	5.98 (↓)	18	18	18
	SF12v2 PCS	>60.04	12.50 (↑)	31.72	34.25	34.80
	SF12v2 MCS	>65.54	11.76 (↑)	22.05	24.10	25.88
PS03	HADS-DS	<8	4.94 (↓)	10	10	8
	BADS-SF	>9.26	9.65 (↑)	24	32	27
	ELS	>45.14	6.86 (↑)	65	58$^{\pm}$	56$^{\pm}$
	MFIS-SF	<2.82	5.98 (↓)	15	15	14
	SF12v2 PCS	>60.04	12.50 (↑)	30.44	29.80	27.89
	SF12v2 MCS	>65.54	11.76 (↑)	34.92	34.66	46.22
PS05	HADS-DS	<8	4.94 (↓)	11	8	4$^{*\pm}$
	BADS-SF	>9.26	9.65 (↑)	12	27*	47*
	ELS	>45.14	6.86 (↑)	35	44*	56$^{*\pm}$
	MFIS-SF	<2.82	5.98 (↓)	16	14	14
	SF12v2 PCS	>60.04	12.50 (↑)	31.48	31.52	30.42
	SF12v2 MCS	>65.54	11.76 (↑)	36	49.40*	58.55*
PS06	HADS-DS	<8	4.94 (↓)	16	10*	4$^{*\pm}$
	BADS-SF	>9.26	9.65 (↑)	27	24	35
	ELS	>45.14	6.86 (↑)	44	49	51$^{*\pm}$
	MFIS-SF	<2.82	5.98 (↓)	19	16	16
	SF12v2 PCS	>60.04	12.50 (↑)	25.66	38.11	29.66
	SF12v2 MCS	>65.54	11.76 (↑)	26.73	31.82	44.66*

Note. This table demonstrates participants' scores on each measure pre-, mid-, and post-intervention.
[a] *RC = reliable change (i.e., minimum change-score required to demonstrate statistically reliable change [at 95% confidence]).*
[b] *Cut off = caseness threshold for determining clinically significant symptoms.*
[c] *Arrows (↑/↓) indicate direction of desired change (improvement) for each measure.*
[d] ** = reliable improvement in relation to first available score.*
[e] *+ = clinically significant improvement in relation to first available score.*
[f] *± = reliable deterioration in relation to first available score*
[g] *HADS-DS, Hospital Anxiety and Depression Scale – depression subscale; BADS-SF, Behavioural Activation for Depression Scale-Short Form; ELS, Engaged Living Scale; MFIS-SF, Modified Fatigue Impact Scale-Short Form, SF12v2 PCS, Short Form 12 version 2 Physical Component Score; SF12v2 MCS, Short Form 12 version 2 Mental Component Score*

Fidelity

A sample of intervention session-recordings were checked for fidelity in terms of adherence to BATD-R session checklist. Six recordings (19% of available recordings) were selected and rated by NM; who had not been involved in intervention delivery. In terms of adherence to session plan, all sampled sessions covered all planned topics (100% adherence) in a suitable flexible and facilitative manner.[20]

Feedback

In total, five change interviews were completed up to two weeks post-intervention. The participant who withdrew from the sessions completed a change interview. Participant 02 who did not complete a change interview reported a relapse in his MS symptoms which he reported negatively impacted his mood and ability to engage in activities.

Overall, reports from change interviews were predominantly congruent with quantitative data (Table 5). Three participants found behavioural activation helpful and attributed change in mood to the intervention. For those not reporting change they found

[20] See Extended Results 3.9 for further details about fidelity

the idea of increasing or identifying activities in the face of physical difficulties hard. Some participants reflected that monitoring their activities and keeping diaries was helpful because they had not realised how low their mood had become. Using the diary provided an opportunity to reflect on week-to-week changes and see how they overcame periods of low mood on certain days. Additionally, planning activities led individuals to look forward to events. For some participants they reported thinking that external events limited the effects of behavioural activation and participant 03 stated that without the intervention she believed her mood would have been worse than at the start.[21]

[21] See Extended Results 3.8 and 3.10 for Change Interviews and participant summaries

560 **Table 5**

561 *Participant change interviews*

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
Experience of Behavioural Activation	Didn't have high expectations as I didn't think things would change. Expectations were minimal, but it highlighted where my problems were, but I didn't overcome them. I don't think asking the same questions of people with secondary progressive MS is of benefit as asking those without. It didn't provide me with solutions to overcome difficulties, but I think that would have been difficult any way.	Very good. When he came to see me, it was lovely to see him, and it made me more interested in the research. I liked the fact I knew somebody was contacting me and I kept diaries. Despite all the life stressors the researcher was a support for me, I knew I could talk to him. He was somebody to offload to and I don't think that I have that. It was really good to have someone there who understands. Reflecting on the diaries allowed me to relay to the researcher. I found the hourly diary a bit too much, but I do like keeping diaries and I did it and managed it.	Too much information to grasp. I know who I am, I know what enjoyment, achievement that I get from the activities I do. I have been alone for a long time and to change lifestyle just was not going to happen. I don't think I could achieve anything better than I am doing as I am set in my ways. I know who I am.	Interesting. I have had therapy before but it usually just talking to someone. But this one was different we did things; it was talking too but we did diaries and I have never thought about writing things down. I am making lists to plan my day now and record what I have done. It was quite new. In comparison to previous therapy this wasn't about getting things off your chest but to do things actively, which made things clearer by writing things down. I am still doing it now and I have bought a journal. It has shown where things have affected me mood wise. I was able to see where I was bringing my mood down and how things were bothering me. I know what makes me feel worse and what makes me feel better.	We had a discussion then he came to see me. I used some diary sheets which I did then when we spoke, we used them, he led me to go back through them to think about when I was down what picked me up. Using that system that is what I am still doing now, to get it in my mind. It seems to be working so far, quite well. At times when I have been down it was hard to complete some days on the diaries, but other than that I have found it useful. It was not that time consuming. The sessions were good, the researcher was pleasant to talk to and he listens and steers you on the

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
					right track which was very good. I found it helpful and would recommend it to anyone else.
Any changes in self or depression	More focused on trying to overcome problems, but unsure if I have made much ground. Very little change in depression, I think I have low mood, but I don't think that I am depressed.	**Positive:** I have been able to express myself. Being able to talk about everything even with everything going on helped. **Negative:** None reported	No changes	**Positive:** I overthink things but now I am putting them into perspective by writing things down and it makes me think about things rationally. I have also started writing down worrying thoughts which has helped. My husband finds me calmer and more relaxed and we have both noticed a difference. I am feeling less tearful and there was one occasion when I received a letter and previously, I would have been vomiting but now I was able to better deal with it. As I make a list of how and when I can tackle parts and build into my week. My mood has increased **Negative:** None reported	**Positive:** I am more positive. My mind has been working on things rather than being in that "can't be bothered place." I look at the diaries and learn what was going on in the past so I can help apply to now. My mood, I feel much brighter. I still experience low mood to an extent, but I suffer from anxiety. My wife has noticed a difference in me. **Negative:** None reported
Attribution to change or non-change	Things are much the same **Therapy:** Focused on what the problems are and thinking about solutions. Solutions were	**Therapy:** I was able to realise in therapy that I am such a determined person.	**Therapy:** I don't think therapy would help because I am set in my ways.	**Therapy:** Using diaries to organise my week which has created lists and has also helped worry.	**Therapy:** Talking to him made me realise, such as if I saw someone struggling

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
	identified but they're difficult and something that needs to be ongoing because of my MS as it will get worse. **External:** Condition dictates how I live my life; it is difficult to make changes to that	Using the diaries and having time to talk was important. It was hard for me to open up as I don't usually do that. **External:** Mum has been ill which has been so upsetting throughout the last few months and having end of life discussions was so hard.	**External:** The physical symptoms of my MS prevent me from changing other things and my reliance on carers. Things are only going to get worse. Anxiety made it difficult because I knew what was going to happen.	**External:** None reported	the way I did what would I say to them because that helped me prioritise, plan, and pace the activities I wanted to do. Using the diaries to reflect on how to plan and overcome. **External:** Talking to my wife and including her, therapy helped me bring it up. So, she can now help put plans in to place as she can notice my mood dropping before sometimes, I realise.
Aspects of life situations to use therapy to deal with problems	**Strengths:** None reported **Stressors:** Mobility, being in a wheelchair, my MS makes it time consuming to do things and therefore I do not have a lot of spare time. My time is taken up by coping with life as it is, which is getting through the day. So, to try and put more into that is very difficult. I cannot cut out those things and adding fatigue makes it difficult to put extra things into my life. Living alone	**Strengths:** I think my determination helped me stick with the therapy, otherwise the fatigue may have wanted me to stop. **Stressors:** Mum has been ill A lot of friends have died	**Strengths:** None reported **Stressors:** Symptoms of MS and the time it takes me to complete activities. What may be a two minute job for someone can take me an hour so I don't have enough time. Living alone.	**Strengths:** Taking each day as I can. I know there is a time when I won't be able to achieve certain things, but I am working out each day. **Stressors:** The MS has made things difficult. My walking has changed which makes me avoid and makes my mood worse if I don't go out. I avoid people who do not know that I have	**Strengths:** Being able to hear the things the researcher picked up and thinking about different ways to try things with that. **Stressors:** None reported

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
	makes it very difficult to make changes, if I was with someone else, they could relieve some pressure to give me more time. I think if I had someone else, therapy would have been easier. Public transport makes accessing activities difficulties because routes and times are set, so I cannot access different things.	I am a support to others with MS which I have found tough to be a support to others and not have support prior to the study for myself.	I can't make a plan of action because I am dependent on others, such as carers.	MS due to worry about their judgement.	
Helpful aspects	Focusing more on what the problems are, I could think about the solutions. Lists of values and process to identify them	It was important that sessions were confidential and gave me space. Somebody to talk to, who is understanding, and confidential. The researcher was a really nice person. Using Skype was good as we could see each other face-to-face. I could see body language and facial expression which you can't on the phone, so you know what the other person is aiming for or getting at. I much preferred that to the telephone, in fact I would like my	Highlighted that I am having to fight for everything. It reinforced knowing that things will happen again and again.	I enjoyed the communication with the researcher as it was a different point of view, the diaries help but the researcher had a different point of view and I am going to miss that. I thought it was sad but then I thought I have these tools and I can use these to help myself. I realised I don't have to beat myself up or stress over things when I have not managed to do some things. I have tried things that I was avoiding by thinking about barriers. I faced things rather than thinking of excuses.	I got back into my hobbies and interests and have made plans for going forward. So, it was helpful to get me there and then doing the activities was helpful. Made me realise that there is a life beyond where I have been. It has picked me up tremendously. It has made me realise I am not just a waste of time. You get to a stage when you think you are hopeless and you try and do something on a bad day and you get frustrated but now I can reflect on it and think on that day I

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
		daughter to Skype now.		I prepare for things if I am not able to do an activity what will I do instead. I think about something else that I can do. Which helps with the diaries and lists. I did not think I would manage the diaries to start with, but it went really well.	can't physically do something so I would do something different or plan when I can next do it.
Unhelpful aspects	Putting in to practice the solutions was hard.	Nothing it was all enjoyable.	The aims of the course, you wanted to try and help me, but nothing was said that I thought could help me.	Nothing, he even introduced me to Skype which I had never done.	None reported
Process of research	Interesting to some extent, it highlighted certain things and focused me on areas of interest in terms of things I should be looking at. You don't usually sit down and make a list of things you are interested in but as life is changing it was helpful to highlight values and interests and how you would like to live your life.	It has been good, beneficial, because it made me realise that I need some help too, rather than me just giving help to everyone else. Someone to talk to and understand.	I was not sure what taking part in the course would lead to. I discontinued the course because I knew what my importance, achievement, and enjoyment would be before completing activities.	The researcher was flexible which in one case was great because we moved a session later in the day which allowed me to achieve one of my goals linked to my values. I've done other research before; I did one by textbook, but I found that hard. In this one it suited me better because there were no medical terms, it was about what I put into it, it is what I got out of it.	Being able to complete online questionnaires was good, because on some evenings when I was experiencing pain or spasms I could do them late at night which took my mind off things.
Changes to quality of life	I wouldn't say I have made many. It was a difficult period of time as I broke my leg 5 months	None reported	None reported	I am getting out more and making sure if something goes wrong, I have a B plan.	It has made me more positive and helped with the communication in

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
	ago which made everything more difficult.				my marriage. My wife thinks I have been more like my old self, laughing and joking.
Changes to fatigue	None	They are about the same	None reported	None, I am going through physio at the moment and that's not helping at the moment. But I try not to let it overwhelm me, if I feel fatigued, I select an activity I can do based on that.	None reported
Best and worst parts of the intervention	**Best:** Providing more focus on what was causing low mood which gives an opportunity to try and improve that. **Worst:** Trying to fit the time in to do the therapy. Day is already quite full so trying to put extra things into my day was not easy, as there is not a lot I can cut out.	**Best:** Skyping with the researcher and being able to talk. **Worst:** Initially, doing the diaries so regularly on the sheets, I found that time consuming.	**Best:** It has highlighted the life I lead and what could be better **Worst:** The ideas that were suggested to me weren't of value because I can't do what others as 'normal' people can do. It has highlighted that I have to put up with how others do activities for me and I cannot control that and what my MS is like.	**Best:** Understanding that I am not alone and there are things that I can do without feeling alone and that there are places I can go to if I need support. **Worst:** Looking at mood and scoring. It seemed important but not that important to me. The part about values was hard to get my head around, I started to get it, but it took longer.	**Best:** It has helped me, and I hope it can help others in the same way. **Worst:** None reported
Explanations for change or lack of change	My MS symptoms have stopped change, although it has been a useful experience despite not	Not being able to do what I want to do in comparison to my health before. I	Having secondary progressive MS would likely give me a different experience to	I started a new medication for pain about the same time as the study which may have helped a little as	None reported

Question	Participant 1 - unchanged	Participant 3 - unchanged	Participant 4 - unchanged	Participant 5 - recovered	Participant 6 - recovered
	making a difference to changing my life.	sometimes want to do more than I can. Mum being unwell really had an impact.	relapse remitting because things are going to get worse no matter what anybody does.	it eased my pain. Although it was making me sleepy and I think the diaries, intervention, and medication all worked together, maybe it was a little bit of everything that has helped change. I couldn't say.	
Ideas for the future	It is possible that because everybody's MS is different it may not work for people. If you don't understand how the condition affects them, it can't be tailored. So, it is a bit general but that may be difficult to change for everyone individual.	Changes to the diary to make them less focused on hour-to-hour but morning, afternoon, and evening.	I think spending more time thinking about goals.	None reported	None reported

562
563 *Note.* Participant descriptions reflect reliable and clinically significant change categories for Hospital Anxiety and Depression – depression
564 subscale. Categories include deteriorated, unchanged, improved, and recovered.
565
566

Discussion

Behavioural activation has long been considered helpful (Cuijpers et al., 2007) though there have been no studies focusing on secondary progressive MS, where physical health and cognition declines. As such, we believe this study makes a useful contribution to the literature.[22] Our findings are comparable to behavioural activation approaches used with individuals with other neurological conditions to reduce depression (Oates et al., 2019).[23] When considering that the treatment approach was predominantly self-directed and short-term in nature, the intervention is promising for those with secondary progressive MS. We hypothesised that an increase in positively reinforcing activating behaviour would reduce depression which was the case in three of five participants. Depression scores reduced as activation increased, upon the introduction of the intervention, which supports the theory that increasing positively reinforcing behaviours reduces depression. Further, in those that did not increase activation behaviours a reduction in depression was not observed.

Based on the results using both conservative dual-criterion and reliable change indices, the criteria to satisfy replicability allows us to conclude that the processes are demonstratable across cases, but with caution (Kratochwill et al., 2010). Caution is suggested because, for the three participants who demonstrated change by one criterion, other change-criteria were not met and there was a desynchrony across markers of change. For example, participant 06 demonstrated systematic improvement using the conservative dual-criterion on the HADS – depression subscale, and demonstrated reliable and clinically significant change on the HADS – depression subscale but did not demonstrate systematic improvement using the conservative dual-criterion between

[22] See Extended Discussion 4.1 for further discussion about effectiveness
[23] See Extended Discussion 4.2 for further discussion about findings in context of previous theory

baseline and intervention for activation on the BADS-SF. In the case of participant 06 the trend from baseline assumed increasing activating behaviours which coincided with reduction in depressive symptoms.

When considering effect sizes using percentage exceeding the median the intervention ranged in effectiveness across all participants from 0.75 to 1 on HADS – depression subscale, which is moderate to highly effective.

Effectiveness of behavioural activation on depression

We hypothesised that behavioural activation would reduce depression, which was arguably seen in participants who reported increased engagement with positively reinforcing behaviours.

Visual analysis suggested that changes occurred gradually and, in most cases, coincided with increased activation on the BADS-SF. One participant remained at the clinical cut off on the HADS- depression subscale. It is possible that some latent effects exist using the HADS. For example, there are some items (e.g., “I feel as if I am slowed down”) that may be insensitive to change in people with secondary progressive MS, because they are likely confounded by physical health states and disability in this population (which could be relatively static or deteriorative), this is despite the fact that the HADS was designed to omit somatic markers of distress/to be apt for use in the context of physical health conditions. However, the inclusion of the HADS was important because the measure has good usage in MS research which allows us to consider changes in respect to other studies (Watson et al., 2014).

We used the suggested cut off for the HADS because it has been used in several MS studies. Alternative cut offs have been suggested for people with MS (such as 11; Watson et al., 2014). Future large-scale studies would be better suited to complete

additional analyses on changes on the HADS-depression subscale when alternative cut-offs are used.

For those that did not demonstrate change, it would be important to understand what, if any, benefits there are to maintain their current state. For some individuals, there may be disincentives (negative consequences) for reporting improvement (e.g., loss of access to supports) which could have influenced responding and/or engagement with the intervention. Ferster (1973) suggested that life events such as reduced social activity, occupational role, or relationship may account for a reduction in daily activity levels. The loss of reinforcement can generalise to other behaviours and may also result in verbal preoccupation which may present as complaints to others about feeling low. The verbal preoccupation may become positively reinforced through peers or therapists in expressions of sympathy or support which can lead to an increase in maladaptive behaviour (Azrin & Besalel, 1981).

Process measure change

Efforts to understand the possible treatment mechanism(s) contributing to the effectiveness of behavioural activation included ratings of activation. As predicted, activation increased where depression reduced. In cases of no change or regression, activation also decreased or did not change. The results were congruent with the theory of Lewinsohn et al. (1976), which postulates that by reducing behaviours that maintain or exacerbate depression and promoting counteracting behaviours depression would reduce.

Regarding values, we hypothesised that during the intervention participants' engaged living scores composed of two subscales (valued living and life fulfilment) would increase. The intervention encouraged participants to identify values and then

pick activities that aligned with those values. Some participants reported it being difficult to identify values whilst others said that they were already aware of them. Six (of ten) questions asked participants whether they were living full lives, whether anything could stop them from doing what they wanted, or whether life is as they intended it to be. It is possible that the nature of their condition resulted in similar pre- and post-intervention scores with few opportunities to demonstrate reliable or clinically significant change. Additionally, in the current format the intervention manual may not have included enough values-directed work to promote values-based activation for some individuals.

During change interviews participants attributed change to reflecting on activity and engaging in enjoyable tasks as opposed to making direct links to valued living, except in one case (PS05) where structuring tasks to values was thought as beneficial.[24]

Quality of life

Throughout the intervention, health related QoL was assessed. No changes were observed in the physical component – which includes physical functioning, pain, general health, and physical roles. Positively, no worsening was observed in physical health QoL. Two participants, who reported increased activation and reduced depressive symptoms demonstrated reliable change on the mental health component, with the third participant demonstrating an increase but it did not fulfil the criteria for reliable change. Whilst depressive symptoms reduced, the intervention did not directly target other factors which can be associated with mental health distress, which may explain the lack of clinically significant change.

[24] See Extended Discussion 4.3 for further discussion about values

664 **Fatigue**

665 Contrary to concerns that behavioural activation may adversely impact fatigue
666 (Sharp et al., 2015), there was no observed impact of behavioural activation (promoting
667 activity) on fatigue in the present study. During the intervention, no changes were
668 reported in fatigue: thus, activation scores (levels of engagement in positively
669 reinforcing behaviour) appeared to vary independently of fatigue.

670 Evaluating fatigue in individuals with depression and secondary progressive MS
671 is not straight forward. For example, fatigue is commonly associated with both
672 depression and secondary progressive MS. A difficulty of studying depression in
673 individuals with secondary progressive MS is that the presence of fatigue in both
674 conditions makes it difficult to attribute the symptom to the disease or depression
675 (Thomas et al., 2006). It is possible that the reduction of fatigue identified in the Proctor
676 et al. (2018) review may be a result of depression related fatigue in early disease
677 formats rather than fatigue which results from the condition.

678 Perhaps positively then, the lack of increased fatigue in participants who
679 increased their activities supports the idea that individuals can increase positively
680 reinforcing behaviours without exacerbating difficulties associated with their condition.
681 Fatigue may contribute to the development, maintenance, and exacerbation of
682 depression by reducing contact with contingencies that were previously reinforcing
683 (Motl et al., 2009), yet with guided self-help some participants were able to identify
684 activities and engage despite the presence of on-going high levels of fatigue.[25]

685

686

[25] See Extended Discussion 4.4 for further discussion about fatigue

Feasibility

During change interviews participants confirmed the acceptability of the materials, measures and sessions. Overall the behavioural activation intervention and methods used in the study were feasible.

Regarding recruitment, we were able to screen and recruit participants who were interested in the intervention. Regarding intervention acceptability, no sessions were missed throughout the study. In terms of participant retention one participant withdrew from the study prior to scheduling activities. Regarding outcome measures, across all participants only four weekly questionnaires were not completed by three participants, and five baseline questionnaires were not completed by three participants.[26]

Strengths and limitations

The study was designed with patient and public involvement (PPI) to investigate suitable interventions to ameliorate depression in secondary progressive MS. PPI input improved the selection of measures, the approach used to complete measures, the acceptability of the language used in the BATD-R, and need for the research.

The design of the study allowed for an investigation of processes that may be associated with therapy. We were able to track changes associated with behavioural activation and the weekly impact on depression. Further, the analysis used triangulation to consider variables and effectiveness. By using visual analysis paired with conservative dual-criterion, percentage exceeding the median, and reliable and clinically significant change indices, we were able to draw conclusions without overstating effectiveness (i.e., reducing Type I and II errors). Using qualitative feedback also

[26] See Extended Discussion 4.5 for further discussion about feasibility

provided explanatory power and added context to data, such as understanding barriers to engaging in positively reinforcing activities and maintaining distress in the face of increasing life stressors.

However, the inclusion of multiple measures with repeated application increases the risk of a Type I error. Further, the repeated administration of measures and the changes to the represented timeframe during the baseline may have compromised the psychometric properties of the measures. As the research was of a preliminary nature, the timeline changes and number of measures were needed to provide an overview of processes and outcomes for behavioural activation on depression in secondary progressive MS.

Additionally, during the baseline phase participants were regularly asked to consider their behaviour and their engagement in positively reinforcing activities. It is possible that behaviour change therefore occurred prior to planning activates and during the activity monitoring phase. The regular support sessions, and every-other-day and weekly outcome measures which were used to strengthen study rigour may have inadvertently impacted validity.

Finally, the intervention used a guided self-help approach. Participants planned and engaged in activities which they reported that they believed would be positively reinforcing in their own time. It is unknown beyond self-report how much someone engaged in their planned tasks. It is possible that demand characteristics led to perceived favourable reporting for behaviour. However, to mitigate this, a positive approach was taken to understanding why non-completion of tasks may have occurred – with the view that all outcomes were positive as they provided new information for the researcher and participant to evaluate.[27]

[27] See Extended Discussion 4.6 for further discussion about strengths and weaknesses

735

736 **Clinical implications and future research**

737 It is too soon to conclude that behavioural activation is an efficacious approach
738 to the treatment of depression for individuals with secondary progressive MS. However,
739 there is potential for behavioural activation to offer alleviation of depression in the face
740 of competing physical symptoms of MS in a manualised and structured time limited
741 intervention that is comparable to IAPT services.

742 Based on beneficial findings for some participants, further investigation is
743 warranted. There is evidence that – despite declining MS symptomology – individuals
744 with secondary progressive MS can identify and engage in positively reinforcing
745 activities, which may then reduce depressive symptomology.

746 This study satisfies Medical Research Council guidance for process evaluation
747 in developing and evaluating complex interventions (Moore et al., 2015). The next stage
748 would be to answer feasibility questions in a trial such as randomising, testing
749 procedures, estimating recruitment and retention, and determining sample size (Craig et
750 al., 2008).

751 Identifying accessible psychological interventions in those with long-term
752 neurological problems is important. Behavioural activation is an acceptable intervention
753 for people with secondary progressive MS, which reduces low mood when engagement
754 in positive reinforcement occurs. Despite increasing activities to engage in positive
755 reinforcement there were no adverse effects to individuals' mental or physical health.
756 The outcomes support the use in clinical practice and warrants further investigation in
757 large groups.[28]

[28] See Extended Discussion 4.7 for further discussion about implications for clinical practice and future research

References

Azrin, N. H., & Besalel, V. A. (1981). An operant reinforcement method of treating depression. *Journal of Behavior Therapy and Experimental Psychiatry, 12*(2), 145-151.

Beck, A. T. (1964). Thinking and depression: II. Theory and therapy. *Archives of General Psychiatry, 10*(6), 561-571.

Bonow, J. T., & Follette, W. C. (2009). Beyond values clarification: addressing client values in clinical behavior analysis. *The Behavior Analyst, 32*(1), 69-84. https://doi.org/10.1007/bf03392176

Chwastiak, L., Ehde, D. M., Gibbons, L. E., Sullivan, M., Bowen, J. D., & Kraft, G. H. (2002). Depressive symptoms and severity of illness in multiple sclerosis: epidemiologic study of a large community sample. *American Journal of Psychiatry, 159*(11), 1862-1868.

Compston, A., & Coles, A. (2008). Multiple sclerosis. *Lancet, 372*(9648), 1502-1517. https://doi.org/10.1016/s0140-6736(08)61620-7

Confavreux, C., & Vukusic, S. (2006). Natural history of multiple sclerosis: a unifying concept. *Brain, 129*(3), 606-616.

781 Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008).
782 Developing and evaluating complex interventions: the new Medical Research
783 Council guidance. *BMJ, 337*, a1655.
784
785 Cuijpers, P., Van Straten, A., & Warmerdam, L. (2007). Behavioral activation
786 treatments of depression: A meta-analysis. *Clinincal Psychology Review, 27*(3),
787 318-326.
788
789 Dimidjian, S., Hollon, S. D., Dobson, K. S., Schmaling, K. B., Kohlenberg, R. J., Addis,
790 M. E., Gallop, R., McGlinchey, J. B., Markley, D. K., & Gollan, J. K. (2006).
791 Randomized trial of behavioral activation, cognitive therapy, and antidepressant
792 medication in the acute treatment of adults with major depression. *Journal of*
793 *Consulting and Clinical Psychology, 74*(4), 658.
794
795 Elliott, R., & Timulak, L. (2005). Descriptive and interpretive approaches to qualitative
796 research. In J. Miles, & P. Gilbert (Eds.), *A Handbook of Research Methods for*
797 *Clinical and Health Psychology* (pp. 147-159). Oxford University Press.
798
799 Ferster, C. B. (1973). A functional analysis of depression. *American Psychologist,*
800 *28*(10), 857-870. https://doi.org/10.1037/h0035605
801
802 Fisher, W. W., Kelley, M. E., & Lomas, J. E. (2003). Visual aids and structured criteria
803 for improving visual inspection and interpretation of single-case designs.
804 *Journal of Applied Behavior Analysis, 36*(3), 387-406.
805 https://doi.org/10.1901/jaba.2003.36-387

Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology, 13*, 117. https://doi.org/10.1186/1471-2288-13-117

Galeazzi, G. M., Ferrari, S., Giaroli, G., Mackinnon, A., Merelli, E., Motti, L., & Rigatelli, M. (2005). Psychiatric disorders and depression in multiple sclerosis outpatients: impact of disability and interferon beta therapy. *Neurological Sciences, 26*(4), 255-262. https://doi.org/10.1007/s10072-005-0468-8

Gawrysiak, M., Nicholas, C., & Hopko, D. R. (2009). Behavioral activation for moderately depressed university students: Randomized controlled trial. *Journal of Counseling Psychology, 56*(3), 468-475. https://doi.org/10.1037/a0016383

Gyani, A., Shafran, R., Layard, R., & Clark, D. M. (2013). Enhancing recovery rates: lessons from year one of IAPT. *Behaviour Research and Therapy, 51*(9), 597-606. https://doi.org/10.1016/j.brat.2013.06.004

Hakim, E. A., Bakheit, A. M. O., Bryant, T. N., Roberts, M. W. H., McIntosh-Michaelis, S. A., Spackman, A. J., Martin, J. P., & McLellan, D. L. (2000). The social impact of multiple sclerosis - a study of 305 patients and their relatives. *Disability and Rehabilitation, 22*(6), 288-293. https://doi.org/10.1080/096382800296755

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (1999). *Acceptance and commitment therapy: An experiential approach to behavior change*. The Guilford Press.

Hind, D., Cotter, J., Thake, A., Bradburn, M., Cooper, C., Isaac, C., & House, A. (2014). Cognitive behavioural therapy for the treatment of depression in people with multiple sclerosis: a systematic review and meta-analysis. *BMC Psychiatry, 14*(1), 5.

Hind, D., Kaklamanou, D., Beever, D., Webster, R., Lee, E., Barkham, M., & Cooper, C. (2016). The assessment of depression in people with multiple sclerosis: a systematic review of psychometric validation studies. *BMC Psychiatry, 16*(1), 278.

Hind, D., O'Cathain, A., Cooper, C. L., Parry, G. D., Isaac, C. L., Rose, A., Martin, L., & Sharrack, B. (2010). The acceptability of computerised cognitive behavioural therapy for the treatment of depression in people with chronic physical disease: a qualitative study of people with multiple sclerosis. *Psychology and Health, 25*(6), 699-712.

Honarmand, K., & Feinstein, A. (2009). Validation of the Hospital Anxiety and Depression Scale for use with multiple sclerosis patients. *Multiple Sclerosis Journal, 15*(12), 1518-1524.

Hopko, D. R., Lejuez, C. W., LePage, J. P., Hopko, S. D., & McNeil, D. W. (2003). A brief behavioral activation treatment for depression. A randomized pilot trial

within an inpatient psychiatric hospital. *Behavior Modification, 27*(4), 458-469. https://doi.org/10.1177/0145445503255489

Jacobson, N. S., Dobson, K. S., Truax, P. A., Addis, M. E., Koerner, K., Gollan, J. K., Gortner, E., & Prince, S. E. (1996). A component analysis of cognitive-behavioral treatment for depression. *Journal of Consulting and Clinical Psychology, 64*(2), 295-304.

Jones, K. H., Ford, D. V., Jones, P. A., John, A., Middleton, R. M., Lockhart-Jones, H., Osborne, L. A., & Noble, J. G. (2012). A large-scale study of anxiety and depression in people with multiple sclerosis: A survey via the web portal of the UK MS Register. *PLoS One, 7*(7), e41910. https://doi.org/10.1371/journal.pone.0041910

Kanter, J. W., Baruch, D. E., & Gaynor, S. T. (2006). Acceptance and commitment therapy and behavioral activation for the treatment of depression: Description and comparison. *The Behavior Analyst, 29*(2), 161-185.

Kanter, J. W., Rusch, L. C., Busch, A. M., & Sedivy, S. K. (2009). Validation of the Behavioral Activation for Depression Scale (BADS) in a community sample with elevated depressive symptoms. *Journal of Psychopathology and Behavioral Assessment, 31*(1), 36-42.

Kanter, J. W., Santiago-Rivera, A. L., Rusch, L. C., Busch, A. M., & West, P. (2010). Initial outcomes of a culturally adapted behavioral activation for Latinas

881 diagnosed with depression at a community clinic. *Behavior Modification, 34*(2),
882 120-144. https://doi.org/10.1177/0145445509359682
883
884 Kratochwill, T., Hitchcock, J., Horner, R., Levin, J. R., Odom, S., Rindskopf, D., &
885 Shadish, W. (2010). Single-case designs technical documentation.
886 http://ies.ed.gov/ncee/wwc/pdf/wwc_scd.pdf.
887
888 Kroenke, K., Spitzer, R. L., & Williams, J. B. (2003). The Patient Health Questionnaire-
889 2: validity of a two-item depression screener. *Medical Care, 41*(11), 1284-1292.
890
891 Lejuez, C. W., Hopko, D. R., Acierno, R., Daughters, S. B., & Pagoto, S. L. (2011). Ten
892 year revision of the brief behavioral activation treatment for depression: revised
893 treatment manual. *Behavior Modification, 35*(2), 111-161.
894
895 Lewinsohn, P. M. (1974). A behavioral approach to depression. *Essential Papers on*
896 *Depression*, 150-172.
897
898 Lewinsohn, P. M., Biglan, A., & Zeiss, A. M. (1976). Behavioral treatment of
899 depression. In P. O. Davidson (Ed.), *Behavioral management of anxiety,*
900 *depression and pain* (pp. 91-146). Brunner/Mazel.
901
902 Ma, H. H. (2006). An alternative method for quantitative synthesis of single-subject
903 researches: percentage of data points exceeding the median. *Behavior*
904 *Modification, 30*(5), 598-617. https://doi.org/10.1177/0145445504272974
905

Manos, R. C., Kanter, J. W., & Luo, W. (2011). The behavioral activation for depression scale–short form: development and validation. *Behavior Therapy, 42*(4), 726-739.

Martell, C. R., Addis, M. E., & Jacobson, N. S. (2001). *Depression in context: Strategies for guided action*. W.W. Norton.

Millefiorini, E., Padovani, A., Pozzilli, C., Loriedo, C., Bastianello, S., Buttinelli, C., Piero, V., & Fieschi, C. (1992). Depression in the early phase of MS: influence of functional disability, cognitive impairment and brain abnormalities. *Acta Neurologica Scandinavica, 86*(4), 354-358.

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D., & Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ, 350*, h1258. https://doi.org/10.1136/bmj.h1258

Motl, R. W., McAuley, E., Snook, E. M., & Gliottoni, R. C. (2009). Physical activity and quality of life in multiple sclerosis: Intermediary roles of disability, fatigue, mood, pain, self-efficacy and social support. *Psychology, Health & Medicine, 14*(1), 111-124.

National Institute for Health and Care Excellence. (2009). *Depression in adults with a chronic physical health problem: recognition and management. (Clinical*

guideline, CG91). Retrieved 27/02/2018 from https://www.nice.org.uk/guidance/cg91

Nicholl, C. R., Lincoln, N. B., Francis, V. M., & Stephan, T. F. (2001). Assessment of emotional problems in people with multiple sclerosis. *Clinical Rehabilitation, 15*(6), 657-668.

Oates, L. L., Moghaddam, N., Evangelou, N., & das Nair, R. (2019). Behavioural activation treatment for depression in individuals with neurological conditions: a systematic review. *Clinical Rehabilitation, 34*(3), 310-319. https://doi.org/https://doi.org/10.1177/0269215519896404

Orlinsky, D. E., Grawe, K., & Parks, B. K. (1994). Process and outcome in psychotherapy. In A. Bergin & S. Grafield (Eds.), *Handbook of psychotherapy and behaviour change* (4th ed.). Wiley.

Patten, S. B., Beck, C. A., Williams, J. V., Barbui, C., & Metz, L. M. (2003). Major depression in multiple sclerosis: a population-based perspective. *Neurology, 61*(11), 1524-1527.

Proctor, B. J., Moghaddam, N., Vogt, W., & das Nair, R. (2018). Telephone psychotherapy in multiple sclerosis: A systematic review and meta-analysis. *Rehabilitation Psychology, 63*(1), 16-28. https://doi.org/10.1037/rep0000182

954 Rejdak, K., Jackson, S., & Giovannoni, G. (2010). Multiple sclerosis: a practical
955 overview for clinicians. *British Medical Bulletin, 95*(1), 79-104.
956
957 Sharpe, M., Goldsmith, K. A., Johnson, A. L., Chalder, T., Walker, J., & White, P. D.
958 (2015). Rehabilitative treatments for chronic fatigue syndrome: long-term
959 follow-up from the PACE trial. *The Lancet Psychiatry*, *2*(12), 1067-1074.
960
961 Siegert, R., & Abernethy, D. (2005). Depression in multiple sclerosis: a review. *Journal*
962 *of Neurology, Neurosurgery & Psychiatry, 76*(4), 469-475.
963
964 Thomas, P. W., Thomas, S., Hillier, C., Galvin, K., & Baker, R. (2006). Psychological
965 interventions for multiple sclerosis. *The Cochrane Database of Systematic*
966 *Reviews*(1), 1-54. https://doi.org/10.1002/14651858.CD004431.pub2
967
968 Thomas, S. A., Coates, E., das Nair, R., Lincoln, N. B., Cooper, C., Palmer, R., Walters,
969 S. J., Latimer, N. R., England, T. J., Mandefield, L., Chater, T., Callaghan, P., &
970 Drummond, A. E. (2016). Behavioural Activation Therapy for Depression after
971 Stroke (BEADS): a study protocol for a feasibility randomised controlled pilot
972 trial of a psychological intervention for post-stroke depression. *Pilot and*
973 *Feasibility Studies, 2*, 45. https://doi.org/10.1186/s40814-016-0072-0
974
975 Trompetter, H. R., Ten Klooster, P. M., Schreurs, K. M., Fledderus, M., Westerhof, G.
976 J., & Bohlmeijer, E. T. (2013). Measuring values and committed action with the
977 Engaged Living Scale (ELS): Psychometric evaluation in a nonclinical sample
978 and a chronic pain sample. *Psychological Assessment, 25*(4), 1235-1246.

Vickrey, B. G., Hays, R. D., Harooni, R., Myers, L. W., & Ellison, G. W. (1995). A health-related quality of life measure for multiple sclerosis. *Quality of Life Research, 4*(3), 187-206.

Wampold, B. E., & Imel, Z. E. (2015). *The great psychotherapy debate: The evidence for what makes psychotherapy work*. Routledge.

Ware, J. J., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233. https://doi.org/10.1097/00005650-199603000-00003

Watson, T. M., Ford, E., Worthington, E., & Lincoln, N. B. (2014). Validation of mood measures for people with multiple sclerosis. *International Journal of MS Care, 16*(2), 105-109.

Wilkinson, H. R., & das Nair, R. (2013). The psychological impact of the unpredictability of multiple sclerosis: a qualitative literature meta-synthesis. *British Journal of Neuroscience Nursing, 9*(4), 172-178. https://doi.org/10.12968/bjnn.2013.9.4.172

Ytterberg, C., Chruzander, C., Backenroth, G., Kierkegaard, M., Ahlström, G., & Gottberg, K. (2017). A qualitative study of cognitive behavioural therapy in multiple sclerosis: experiences of psychotherapists. *International Journal of Qualitative Studies on Health and Well-being, 12*(1), 1325673.

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica, 67*(6), 361-370.

Extended Paper

1. Extended introduction

1.1 Neurological conditions

Neurological conditions are diseases of the central and peripheral nervous system, which can affect the brain, autonomic nervous system, cranial nerves, peripheral nerves, nerve roots, spinal cord, neuromuscular junction, and muscles (World Health Organization, 2016). In total there are over 600 types of neurological conditions, which have been categorised into sudden onset (e.g., brain or spinal cord injury), progressive (e.g., late stage multiple sclerosis [MS], Parkinson's, or motor neuron disease), intermittent and unpredictable (e.g., epilepsy, migraine, early stage MS, or myalgic encephalomyelitis), and stable neurological conditions (e.g., post-polio syndrome; NHS England, n.d.), which may be a result of illness or injury (Neurological Alliance, 2003; World Health Organization, 2006). In literature, neurological conditions have been reported individually (as their own classification) and sub-categorised as part of the larger umbrella term of long-term conditions (Kings Fund, 2012; National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010; NHS England, n.d). The use of individual and sub-categorisation can present difficulties when attempting to synthesise existing literature, which impacts our ability to further develop our understanding of the associated difficulties people experience because data are often amalgamated. Further, the impact of this wider grouping means that policy guidance and impact reports contain an array of symptoms and experiences making understanding individual conditions, or types of conditions difficult.

1.1.2 Prevalence and impact of neurological conditions

In England, in 2012, the prevalence of individuals who have one or more long-term condition (inclusive of neurological conditions) was reported to be more than 15 million people (30% of the population; Kings Fund, 2012). However, in 2014, estimates for people living with a neurological condition that has a significant impact on their lives in the UK, were reported to be as high as 12.5 million. It is estimated in England that over 800,000 people have Alzheimer's/dementia (Prince et al., 2014), 135,000 people have a brain injury (McMillan & Greenwood, 1991), 300,000 people have epilepsy (Hart et al., 1990), 127,000 people have MS (MS Society, 2018a), 215,000 people have myalgic encephalomyelitis (National Institute for Health and Care Excellence, 2007), 120,000 people have Parkinson's disease (Parkinson's UK, 2018), and 300,000 people have had a stroke (Geddes et al., 1996; Oxfordshire Community Stroke Project, 1983). The figures demonstrate the increasing incidence of people living with a neurological condition and the difficulties associated with prevalence estimates.

1.2 Multiple Sclerosis

MS is a chronic neurological condition that affects the central nervous system. MS affects over 100,000 people in the UK (MS Society, 2018a). The majority of individuals are diagnosed between 30 and 40-years of age, with a higher prevalence in females than males (Mackenzie et al., 2014).

MS is caused by the demyelination of axons; damage to the protective layer, known as the myelin sheath, that surrounds nerves. Demyelination results in scar tissue on the axons which causes nerve damage known as lesions or plaques (Smith & McDonald, 1999).

The aetiology of MS and the demyelination of axons is unknown (Smith & McDonald, 1999), but several risk factors have been identified such as genetics, infection, vitamin D deficiency, smoking, exposure to certain solvents, and obesity (Gilden, 2005; MS Trust, 2018). However, the risk factors for MS are very common, with thousands of individuals exposed to them daily, yet only a small number of people develop MS. It is likely that a combination of factors are needed for the development of MS (MS Trust, 2018). It is widely theorised that MS is an autoimmune disorder, where the body's immune system attacks the individual's tissues rather than germs.

Four subtypes of MS exist. They are relapse remitting, primary progressive, secondary progressive, and benign. Individuals with benign MS show no symptoms and have minimal disability over a period of many years; typically, individuals are symptomless for over 15-years (Lassmann et al., 2001). The remaining subtypes are categorised by the course of the disease and symptom presentation. Around 85% of individuals are initially diagnosed with relapse remitting MS (Rejdak et al., 2010). Relapse remitting MS is characterised by the sudden onset of symptoms which last on average two to six weeks before symptoms completely remit (Rejdak et al., 2010).

Primary progressive MS describes the trajectory of the disease; in which symptoms are present and progressively worsen from the onset of the disease. Contrastingly, in the later years those with relapse remitting MS experience episodes of symptom presentation that do not retreat; leading neurologists to confirm transition to secondary progressive MS. Individuals have a variety of symptoms that may include difficulties with vision, balance, fatigue, pain, and cognition (Rejdak et al., 2010). The symptoms experienced by individuals with MS vary; based upon the areas of the nervous system that are affected and the type of MS (Jones et al., 2008). MS can also have a number of

effects on psychological wellbeing (Wilkinson & das Nair, 2013), presenting individuals with a need for psychotherapy, that is both effective and accessible considering the physiological impact of the disease.

1.2.1 Secondary Progressive Multiple Sclerosis

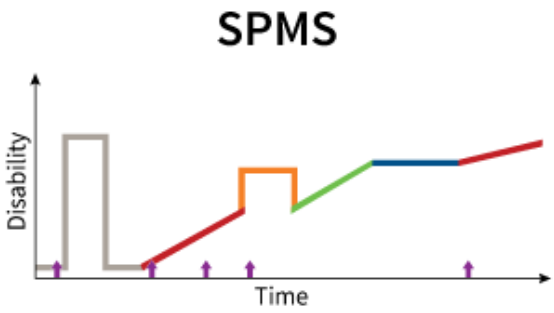
In the UK the prevalence of individuals with secondary progressive MS is estimated to be 57.8/100,000 (40.9–74.6/100,000; Khurana et al., 2018). Individuals with secondary progressive MS experience gradually worsening symptoms that can include increased weakness, difficulties with coordination, muscle stiffness, bowel and bladder problems and troubles with fatigue, depression, and cognition (Compston & Coles, 2008).

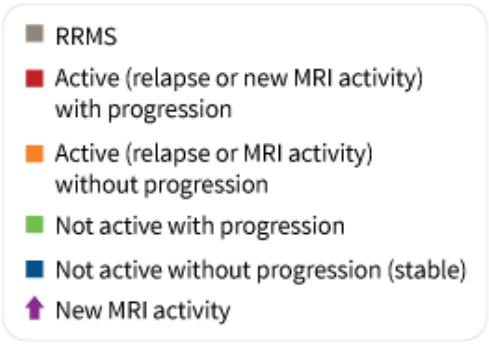
Individuals with secondary progressive MS who experience cognitive symptoms can have difficulties with short-term memory, word finding, concentration, and processing (MS Trust, 2018). Fatigue is another common symptom for individuals with secondary progressive MS. Individuals experience fatigue as exhaustion which is disproportionally related to a task that the person has engaged in and presents as both physical and mental tiredness (MS Trust, 2018). The symptoms that individuals experience depend on the location of the lesions located on their brain and spinal cord (MS Trust, 2018), meaning individuals can have unique symptom presentation.

Secondary progressive MS is characterised at different time points as either active, with relapses/or evidence of new MRI activity, or not active. Additionally, time points are with progression (worsening disease, with or without relapses) or without progression (National Multiple Sclerosis Society, n.d) as seen in Figure 5.

Figure 5

Secondary progressive multiple sclerosis disability progression





Source: Lublin et al., 2014.

Note. This figure details an example of disability over time in secondary progressive multiple sclerosis. Increased disability is represented by increased distance from 0 on the y axis.
[a]Secondary progressive multiple sclerosis progression. (Lublin et al., 2014)
[b]RRMS, relapse remitting multiple sclerosis; MRI, Magnetic Resonance Imaging.

To manage symptoms, individuals maintain a pharmacological regimen therefore identifying psychological interventions to manage mood rather than using medication may be of benefit, as it reduces the number of medications that people take.

1.3 Depression

Depression is a disorder characterised by low mood and/or loss of pleasure in activities accompanied by a range of physical, emotional, cognitive, and behavioural symptoms (National Institute for Health and

Care Excellence, 2015). The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) defines depression as the presence of five of nine symptoms present for two weeks.

The DSM-5 is used to diagnose major depressive disorder by asking questions about two core symptoms, feeling down, depressed, or hopeless during the last month, and having little interest or pleasure in doing things. If the individual has had the presence of the symptoms most days for at least two weeks other typical symptoms are investigated. Symptoms include fatigue/loss of energy; worthlessness/excessive or inappropriate guilt; recurrent thoughts of death, suicidal thoughts, or actual suicide attempts; diminished ability to think/concentrate or indecisiveness; psychomotor agitation or retardation; insomnia/hypersomnia; and significant appetite and/or weight loss.

The lifetime prevalence of depression is estimated to be 16% (Kessler, Berglund, et al., 2005) and single year prevalence is 4% (Kessler, Chiu, et al., 2005). Approximately 25% of individuals with two or more chronic health problems have depression compared to 3% of individuals who are physically healthy (Moussavi et al., 2007). Additionally, stressful life events and low socioeconomic status are associated with increased risk of depression (Monroe et al., 1999). Treatment for depression is sought by one in four women and one in ten men during their lifetimes (National Institute for Health and Care Excellence, 2015). However, the increased rates of depression in females versus males may be the result of differences in reporting (Kessler et al., 2003).

1.3.1 Theories of depression

There are a number of theories for the onset and maintenance of depression. Indeed, within certain schools often more than one theory exists. For example, early psychodynamic theories of depression posit that depression is the result of intrapsychic conflict of conscious and subconscious (Freud, 1992). More recently, object relations theory posits that depression is caused by difficulties individuals have with the development of their representations of healthy relationships. Depression results due to a conflict that individuals endure when attempting to maintain contact with desired objects (Greenberg & Mitchell, 1983).

Cognitive theorists posit that depression is the result of faulty thinking processes (Beck, 1963, 1964) and that thoughts, feelings, and behaviour are interrelated and influence each other bidirectionally (Center for Substance Abuse Treatment, 1999). Individuals' emotions and behaviours are affected by cognitive factors including perceptions, attitudes, beliefs, cognitive schema (Kibler, 2011), and attributions (Clore & Huntsinger, 2007). The cognitive factors are used as a template to appraise events. Beck (1967) proposed that three mechanisms are responsible for the development of depression, the cognitive triad of negative automatic thoughts, errors in logic, and negative self-schemas. Within the mechanisms, individuals with depression hold negative views of themselves, the world, and the future (Beck, 1967) resulting in negative self-schemas. The negative self-schemas result in individuals misperceiving events as they process information from events in a distorted and negatively biased fashion. Individuals also ruminate on negative elements of their lives then the self-defeating interpretations of events maintain the cognitive triad (Beck, 1967). The development of the negative self-schemas can result

from a number of experiences such as rejection, loss, abuse, or criticism. However, the presence of the negative self-schema predisposes an individual to depression, but the cognitive triad and schema are activated only in the face of a stressful life event (Beck et al., 1979).

Systemic theorists posit that psychological distress is the result of interpersonal relationships (Vetere & Dallos, 2003), therefore psychological distress does not result from an individual's psychology, but, is the result of an intricate iterative process that is best understood as relationship dynamics at several levels (Vetere & Dallos, 2003).

Systems theory underpins systemic approaches to psychological distress and provided a conceptual shift in the understanding of human behaviour; moving from linear to circular causation (Vetere & Dallos, 2003). Circularity describes how feedback loops explain the maintenance of anxiety, stress, or distress within a system (Tomm, 1987a, 1987b, 1988). Further, circularity describes how changes in symptoms effect the system (Gar & Hudson, 2009). Over half of people with depression experience problematic and stressful family functioning (Coyne et al., 2002) and access to social support is correlated with depression (Harandi et al., 2017).

1.3.1.2 Behavioural theory

Behaviourism is a psychological approach which uses scientific and objective methods for investigating phenomena (Watson, 1913). Behavioural theory posits that all behaviours are acquired through conditioning through a person's interactions with their environment. Therefore, a person's actions are influenced by their responses to environmental stimuli (Stout, 2003).

Traditionally, behaviourism was primarily concerned with observable behaviour, as opposed to internal events like thinking and emotion (methodological behaviourism associated with J Watson). However, radical behaviourism – most notably associated with B.F. Skinner – argues that internal events (thoughts) should be explained in the analysis of behaviour (Dawson et al., 2015). Behavioural analysis is concerned with conditioned behaviour. There are two major types of conditioning, classical and operant.

Classical conditioning which is a theory of learning and describes the acquisition of a behaviour has been tested and demonstrated in laboratory settings (Pavlov, 1902). Within an individual's environment certain environmental stimuli can produce a reflexive response (i.e., unconditioned stimulus results in an unconditioned response). The reflexive response can be elicited by pairing the unconditioned stimulus to a neutral stimulus (Gottlieb & Begej, 2014). Following repetition, it is possible to use the neutral stimulus to elicit the reflexive response in the absence of the unconditioned stimulus; through paired association. The paired association results in the unconditioned response becoming a conditioned response.

Operant conditioning describes the maintenance of a behaviour. Specifically, that the frequency of a behaviour is controlled by its consequences (Skinner, 1953). Factors such as the prominence of the stimulus or the timing of the presentation effect the speed in which an association is made (Skinner, 1948). Skinner (1974) stated that psychology should be used as an experimental science that should aim to predict and control behaviour by exploring functional relationships that exist between control variables and behaviours. Skinner defined behaviour as anything that an individual does; including internal events such as thought (Skinner, 1974). Operant conditioning experiments

demonstrated that behaviour is influenced by both what happens before (classical conditioning) and what happens after an event.

Skinner describes four consequences following an event that alter the frequency of a behaviour. The consequences fall in to two categories; reinforcement or punishment (Murphy & Lupfer, 2014).

When the consequence of a behaviour increases its frequency, it is known as reinforcement, which can either be positive or negative. Positive reinforcement occurs when a rewarding stimulus is presented following a behaviour that increases the frequency of the behaviour (Murphy & Lupfer, 2014). Negative reinforcement occurs when a stimulus is not presented or removed following a behaviour that increases the frequency of the behaviour (Murphy & Lupfer, 2014). Positive and negative reinforcement occur naturally within the environment (Skinner, 1953) and the timing and pattern of reinforcement impacts both the speed of acquisition and the time it takes for a behaviour to become extinct, in the absence of reinforcement (Skinner, 1948).

The second type of consequence, punishment, can also be positive or negative. Punishment occurs when a stimulus decreases a behaviour. A positive punishment is when the presence of a stimulus reduces behaviour and negative punishment occurs when the removal of a stimulus decreases behaviour (Murphy & Lupfer, 2014).

Another factor that influences behaviour is the timing of reinforcement, known as schedules of reinforcement. Four types of schedules exist, continuous, intermittent, ratio (fixed and variable), and interval (fixed and variable; Ferster & Skinner, 1957). Continuous reinforcement is when a behaviour is reinforced every time it occurs. Intermittent reinforcement is when a behaviour is reinforced on some occasions and

not others; intermittent reinforcement can be at fixed-ratio (set after a specified number of occurrences) and variable-ratio (unpredictable pattern).

Extinction (ending a behaviour) happens when the association between stimuli ends which causes the behaviour to weaken or stop. The rate of extinction is affected by the original response, for example, the longer a response has been conditioned the longer it can take for the behaviour to become extinct (Skinner, 1948). In depression, operant conditioning explains the maintenance of behaviour (including avoidance) as a result of maladaptive coping strategies.

1.3.1.3 Behaviourism and depression

Ferster (1973) theorised that the reduced levels of activity observed in individuals with depression was the result of a lack of reinforcement in those activities/behaviours. A number of factors can lead to the reduction in reinforcement, such as loss of a relationship or occupation which reduces social activity and results in the removal of positive reinforcement for both social behaviours and the behaviours that precede the activity, such as leaving the house or contacting friends. Individuals with MS experience a number of changes which may further impact opportunities for positive reinforcement such as reducing mobility and reduction in cognitive functioning that may exclude them from previously reinforcing activities. The loss of reinforcement can generalise to further behaviours, for example, by reducing social behaviours, a reduction in behaviours such as eating which has physiological reinforcers may occur. The behaviour can be affected due to the often intrinsically social aspect of eating.

An association between the severity of depression and rate of positive reinforcement supports the idea that a reduction in positive

reinforcement can lead to worsening depression (Lewinsohn & Libet, 1972). However, the study was unable to prove causality and it is feasible that the findings highlight what is known; depressed individuals engage in less activities than non-depressed individuals and reduce their contact with social activities.

Once an individual's behaviour has changed and they lose contact with their activities the person may develop a verbal preoccupation with their loss. The verbal preoccupation may present in the shape of crying, complaining to others, or expressing suicidal ideation. The verbal behaviour may be positively reinforced by individuals around the depressed person as the system offer sympathy, leading to an increase in the unhelpful behaviour (Azrin & Besalel, 1981). Over time, individuals experience reduced opportunity for reinforcement from helpful behaviours and experience increased opportunity for reinforcement of maladaptive behaviours. The maladaptive behaviours become the individual's chief means of accessing reinforcement.

Negative reinforcement occurs when individuals engage in avoidant behaviours because aversive emotions are removed. For example, avoiding a friend who tells them "just cheer up, it can't be all that bad" or a critical friend who appears blaming means that the shame or guilt that an individual may experience is removed, therefore the avoidant behaviour is negatively reinforced and increases the likelihood of further avoidance (Lewinsohn, 1974).

1.3.2 Depression and multiple sclerosis

People who have neurological conditions can experience difficulties that can weaken or disable them for periods of time (NHS England, n.d). Specifically, people can experience problems with fatigue, memory, mobility, apathy, cognition, anxiety, and depression (National

Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010; National Institute for Health and Care Excellence, 2009). People with a long-term and/or neurological condition are two to three times more likely to experience mental health problems, than those without a long-term and/or neurological condition, and there is an independent association between physical illness and emotional distress (Kings Fund, 2012). In individuals with neurological conditions depression is frequently underdiagnosed. For example, depression is underdiagnosed and undertreated in individuals with Parkinson's disease (Quelhas & Costa, 2009), MS (Skokou et al., 2012), Alzheimer's disease (Starkstein & Mizrahi, 2006), and epilepsy (Trivedi & Kurian, 2007). The underdiagnosis in people with neurological conditions might be explained by difficulties in distinguishing between neurological and depressive symptoms, which may be further exacerbated by communication difficulties experienced by individuals with neurological impairment, which makes ordinary screening methods less effective (Rickards, 2006).

As a result of diagnosis difficulties, the estimated prevalence of depression in specific neurological conditions vary greatly (Thielscher et al., 2013). For example, lifetime risk of depression in people with MS has been reported to be between 40-60% (Sadovnick et al., 1996), in Parkinson's disease 7-76% (Veazey et al., 2005), in Alzheimer's 30-50% (Holtzer et al., 2005), in epilepsy 9-58% (Harden, 2002), and 33-61% in brain injury (Jorge et al., 2004; Kim et al., 2007). It is possible that estimates vary so widely due to the wide range of psychometrics and variability in assessments, differences in diagnostic criteria, and the overlap with co-morbid symptoms of the condition itself such as fatigue (Boyle, 2007). In addition, the known presence or discovery of a chronic physical health problem can result in the physician's attention being focused on the individual's physical condition, leading to

depression being overlooked (Thompson et al., 2009; Tiemens et al., 1999).

Overlooking depression is problematic because depression is a common co-morbidity in people with MS. Psychological difficulties and psychosocial problems are highly prevalent in individuals with MS and can result from factors such as fatigue, physical disability, cognitive changes, pain, and difficulties with receiving support from others (Khan et al., 2007). Indeed, prevalence rates of depression in people with MS are higher than in that of other conditions and the general public (Galeazzi et al., 2005; Patten et al., 2003). Further complications associated with depression in MS include breakdown in employment, medication adherence, increased risk of self-harm, and suicide and depression (Hind et al., 2014).

When considering the aetiologies of depression described above and the physiological experience of those with MS, additional theories warrant consideration in individuals with MS. Depression may be a result of MS specific immune dysregulation, iatrogenic effects of MS medication, or neurological damage (Mohr & Cox, 2001). It has been hypothesised that depression may be an effect independent of the disease but may be maintained by the MS (Galeazzi et al., 2005). Further, additional factors such as prolonged periods of uncertainty, loss of social support, and reduction in daily functioning contribute to the ongoing maintenance of depression (Barnwell & Kavanagh, 1997; Mullins et al., 2001).

One difficulty in the study of MS and depression is the presence of mutual symptoms. For example, fatigue is a symptom of both MS and depression which makes it difficult for researchers to attribute the presence or on-going presence of a symptom to either MS or depression (Thomas et al., 2006).

1.3.3 The maintenance and impact of co-morbidity

Depression may be maintained in individuals with MS due to a reduction in an individual's social and leisure activities (Hakim et al., 2000; Motl et al., 2009). It is important that depression is recognised and treated in individuals with MS because the presence of depression is associated with poorer self-management of the individual's condition, which reduces quality of life (Katon, 2003). Further, when people experience depression in addition to their neurological condition, co-morbidity has an adverse effect on an individual's frequency of hospital admissions, duration of hospital stays, engagement in treatment, and treatment outcomes (Price et al., 2011). Co-morbid mental health problems and neurological conditions are also associated with increased mortality rates (Kings Fund, 2012). The resulting difficulties that individuals experience with self-management (i.e., medication and appointment adherence) and the on-going presence of depression, also has a huge impact on the costs that healthcare services have to bear (Kings Fund, 2012).

1.3.4 Impact of depression in people with multiple sclerosis

In 2015, the UK per-subject cost per year for people with MS was categorised as severe by the Expanded Disability Status Scale at around £40,000 (Kobelt et al., 2017). The costs include direct healthcare, disease modifying treatment, services, informal care, and production losses, however, individual breakdowns for mental health costs are not provided. There is debate amongst researchers about the relationship between functional disability and depression, with some studies reporting a relationship between depression and greater disability and others claiming depressive episodes are independent of symptom severity (Chwastiak et al., 2002; Millefiorini et al., 1992).

People with MS reduce their social and leisure time activities following a diagnosis of MS (Hakim et al., 2000), which is unfortunate because these activities are known to improve mood (Motl et al., 2009). Reduction in activities may be because of mood problems, or other disabilities caused by MS, but there is a cyclical effect: low mood to fewer activities to low mood. People with MS are unable to engage in activities they previously did and may struggle to find new activities to replace them (Motl et al., 2009). Whether the cause of reduced pleasurable activity results from fatigue and disability, or mood-related loss of interest, the lack of activity can theoretically contribute to the development, maintenance, and exacerbation of low mood (through loss of contact with contingencies that were previously reinforcing and mood-enhancing).

People with MS also experience cognitive dysfunction which affects between 40-70% of people with MS (Benedict et al., 2006; Strober et al., 2014). Cognitive dysfunction may be exacerbated by depression as depression can cause significant changes in behaviour which can influence the indices of cognitive reserve. Therefore, successfully treating depression may lead to a more active lifestyle thereby off-setting in part the cognitive burden of disease.

When considering the increased cost to services, impact on patient outcomes, and decreased quality of life it is important to understand the most appropriate treatment for depression.

1.4 Psychological interventions in people with neurological conditions

When depression is present with reduced or declining physical abilities (common in many neurological conditions), individuals find it difficult

to identify with and engage in activities that have pleasurable or reinforcing consequences (Kanter et al., 2006).

In the UK, National Institute of Health and Clinical Excellence recommends the use of cognitive behavioural therapy (CBT) for treating depression in individuals with chronic physical health problems (including neurological conditions; National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010). CBT is a short-term, often time-limited, psychotherapy aimed at problem solving by reappraising negative thinking that is impacting on emotions and behaviours (Beck, 1964). However, CBT is not best suited for people with chronic health difficulties (Hind et al., 2010), because many have cognitive difficulties that may make accessing and engaging with CBT difficult (Hind et al., 2014). Therefore, adapting psychological therapies to better consider the interaction of co-morbid psychological and physical conditions may be more acceptable to people with neurological/physical health conditions (Cully et al., 2009).

Due to the nature of the condition (MS) accessing face-to-face therapy can be difficult and expensive (Fletcher et al., 2006; National Institute for Health and Care Excellence, 2006) which has led to studies investigating the effectiveness of CBT using technology-based formats (Hind et al., 2010); following National Institute for Health and Care Excellence (NICE) recommendations for computerised CBT or telephone interventions for mild to moderate depression. In MS the presence of chronic physical illness can make psychological interventions difficult, but not without success (Cooper et al., 2011; Mohr et al., 2000).

1.4.1 Psychological interventions in people with multiple sclerosis

The NICE guidance for the treatment of depression for people with MS refers clinicians to the NICE guideline on depression in adults with a chronic physical health problem (National Institute for Health and Care Excellence, 2014). Whilst the MS guidance does not recommend specific interventions it highlights the need for, and potential benefits of, providing emotional support (National Institute for Health and Care Excellence, 2014).

To improve accessibility to help individuals access the potential benefits of emotional support, CBT should be adapted to consider frequency and length, duration of sessions, and to incorporate physical health care with mental health care (National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010).

CBT has been shown to improve depression in individuals with chronic physical health problems. Effect sizes favour CBT over standard care, with small-to-moderate effects observed when CBT is delivered as an individual intervention (.20-.55) and moderate effects when delivered as a group intervention (.58; Farrand & Woodford, 2015; Rizzo et al., 2011; van Straten et al., 2010). One purported reason for the small to medium effect sizes is that standardised CBT interventions are not best suited for people with chronic health difficulties (Hind et al., 2010). In addition, many individuals with neurological conditions have cognitive difficulties which may make accessing and engaging in CBT and the materials difficult (Hind et al., 2014). Indeed, when individuals have difficulty engaging in materials rates of attrition are increased (Fitzpatrick et al., 2010). Therefore, adapting psychological therapies to better consider the interaction of co-morbid psychological and

physical conditions may be more acceptable to people with neurological/chronic physical ill health conditions (Cully et al., 2009). As a result, there may be opportunity for an evaluation of effective psychological treatments for depression in people with neurological conditions.

As secondary progressive MS is a progressive disease and an individual's disability worsens over time understanding the effectiveness of interventions at various disease stages is important; as, favourable approaches may only be helpful for individuals with minor disability issues. A review of psychological interventions for people with MS organised the findings in to four sub-groups: people with cognitive impairments, people with moderate to severe disability, people with MS (no other criteria), and people with depression (Thomas et al., 2006). The authors of the review found 16 psychological intervention studies for people with MS on outcomes for depression, anxiety, disability, cognitive functioning, self-esteem, and self-efficacy. The evidence suggested the use of CBT showed improvements for people with depression (Thomas et al., 2006). However, the studies in the review had small sample sizes increasing the risk of a type 2 error. Further, the review found only three trials for participants (n=80) with moderate to severe disability and only one trial reported favourable outcomes for psychotherapy for depression.

An alternative approach to CBT may be behavioural activation. NICE recommended that behavioural activation be compared with antidepressant medication for treating depression for people who have chronic physical illness, to investigate the clinical and cost effectiveness of behavioural activation (National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010). The importance of future research in this area is a result of limited existing evidence for the effectiveness of high-intensity

psychological interventions, in this population, to treat moderate to severe depression. Currently, the most substantial evidence base for the treatment of depression in this population is CBT, however there have been recent studies that suggest behavioural activation may be effective (National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010).

1.5 Telephone based interventions

Due to the costs of psychotherapy, lack of services for individuals who live in rural areas, and the complications that physical difficulties or fatigue can create for individuals travelling to appointments, modalities other than face-to-face warrant investigation. Telephone can be used for a number of health care activities, including diagnosis, emotional support, medication and symptom management, and physical and mental health interventions. Telephone-psychotherapy allows an individual to access psychological therapies from their own homes and reduces travel costs incurred by some community-based therapists.

Telephone-psychotherapy works in the same way as face-to-face therapy; however, telephone-psychotherapy may have lower attrition rates than face-to-face therapy (Mohr et al., 2008). Individuals are often satisfied and accepting of telephone-psychotherapy (Bee et al., 2008), however, clinical experience tells us that some individuals dislike telephone-psychotherapy due to not being able to see who they are talking to; making it difficult to engage emotionally. Despite the differing user experience of telephone-psychotherapy several reviews have indicated the potential effectiveness of telephone-psychotherapy in individuals with a range of physical and mental health difficulties (Hailey et al., 2011; Leach & Christensen, 2006), including those who have had a stroke (Johansson & Wild, 2011).

In a systematic review and meta-analysis of telephone psychotherapy for people with MS positive treatment effects were found for outcomes of depression, physical activity, quality of life, fatigue, MS symptoms, and medication adherence (Proctor et al., 2018). The authors of the review identified 11 randomised-controlled trials, with 1104 participants, assessing the effectiveness of telephone-psychotherapy for people with MS compared to no care, treatment as usual, and other controls. Ten studies were included in the meta-analysis and a moderate effect size was found for depression favouring the intervention (SMD = 0.47, 95% CI 0.21- 0.73). However, the studies included in the review were of poor methodological quality. The included studies were predominantly CBT and whilst immediate post-intervention benefits were observed they were not sustained in the long-term.

In addition to telephone-psychotherapy a number of computerised CBT interventions have been investigated. In a recent narrative review (Ratajska et al., 2019), authors conclude that despite difficulties in recruitment and high dropouts, in interventions without human support, (Richards & Richardson, 2012) that computerised interventions have the potential to benefit patients. However, the review has a number of methodological issues, such as not outlining a search strategy or assessing included studies' quality meaning that an assessment of effectiveness should be made with caution.

Like much of the research published on interventions for people with MS there is a sparsity of investigations into the effects of telephone-psychotherapy for people with secondary progressive MS.

1.5.1 Mechanisms of change in internet/telephone therapies

Approaches used in telephone-psychotherapy are thought to engender change in the same way that face-to-face psychotherapy. Telephone-psychotherapy uses psychoeducation, techniques specific to the therapy modality, and therapeutic rapport (Wampold & Imel, 2015). Strong therapeutic rapport has been found to improve outcomes in telephone-psychotherapy for people with MS (Beckner et al., 2007) however the study design was unable to demonstrate mechanisms of change.

1.5.2 Face-to-face vs technology-based communication therapy

When compared to face-to-face interventions, telephone-psychotherapy interventions are equally comparable (Brenes et al., 2011). Telephone-psychotherapy appears to offer increased opportunity to access therapy as attrition is lower in telephone-psychotherapy than face-to-face interventions in individuals with depression (Mohr et al., 2008).

1.5.3 Rationale for telephone internet-calling in multiple sclerosis

The application of telephone-psychotherapy and mechanisms for change utilises similar methods to face-to-face interventions. There is growing evidence for the effectiveness of telephone-based approaches; despite methodological issues which affected the quality of the studies included in reviews. In a recent meta-analysis investigating the effectiveness of telephone-psychotherapy in people with MS small to moderate effects were identified (Proctor et al., 2018) but higher quality studies were needed. Telephone-psychotherapy offers a practical solution to overcoming physical difficulties that people with secondary progressive MS experience. For individuals who are unable to travel to appointments due to their symptoms such as fatigue,

telephone-psychotherapy supports individuals to continue to access support when most needed.

1.5.4 Guided self-help

Guided self-help is a NICE recommended treatment for depression and anxiety. Guided self-help is usually short-term, supported with materials, and delivered by individuals with training in delivering psychotherapies. The aim of guided self-help is to support an individual to make changes to make positive changes to mood. The approach encourages individuals to develop a collection of resources in order to enable them to be their own 'therapist' in the future. The approach aims to improve an individual's sense of agency, as individuals are able to make their own changes, thus, encouraging them to draw on the resources they acquired in any future occurrences of psychological difficulties.

In the general population the evidence for the effectiveness of self-help versus face-to-face interventions is varied. For example, no significant difference was found between face-to-face and self-help interventions for depression or anxiety (Cuijpers et al., 2010). Whilst the findings were not significant a small effect size was identified favouring guided self-help. Contrastingly, in a review investigating the efficacy and acceptability of self-help interventions for anxiety, face-to-face interventions were more effective than telephone-psychotherapy. However, the review did highlight a significant effect size (.84) in favour of self-help versus wait list controls. The review also highlighted a significant effect size for the use of supported self-help versus no guidance (.34), indicating that the addition of someone to give guidance or web-based interventions improved treatment outcomes.

1.5.4.1 Guided self-help in multiple sclerosis

Guided self-help interventions have been researched in individuals with MS and findings have demonstrated the effectiveness of the approach. For example, when compared to usual care, an eight-week, guided, telephone CBT intervention showed a reduction in pre- and post-intervention scores for depression ($F(1, 21) = 15.37$, $p < .001$; Mohr et al., 2000). There were only 32 participants in the intervention group so further higher-powered research is required, however, the findings indicate the potential utility of combining telephone-psychotherapy, guided by clinicians and making use of homework tasks and materials. Mohr et al. (2000) also indicate that the utilisation of telephone-psychotherapy is a more beneficial approach than face-to-face interventions for individuals who have difficulties to attend regular appointments due to symptoms that result from their condition such as fatigue.

More recently, a randomised-controlled trial using cognitive-behavioural telephone-psychotherapy for people with MS compared intervention group to an educational control group (Ehde et al., 2015). The educational control group consisted of symptom education and management. The control intervention was developed to account for therapeutic rapport, participating in a manualised intervention, and treatment dosing. The research showed that all participants significantly improved on depression, pain, and fatigue measures from pre- to post-intervention. The researchers had hypothesised that there would be a significant difference between the two groups, however, none was found. However, individuals in the cognitive-behavioural telephone-psychotherapy group had significantly higher levels of treatment satisfaction, mood, social roles, and activation which were maintained at long-term follow up.

In a recent review of the effectiveness of self-management interventions in individuals with MS for depression, anxiety, and quality of life, three of five studies reported reduction in depression (Kidd et al., 2017). However, only one of the three studies reported a significant difference to a control group. The Ehde et al. (2015) study was also included in the review and showed significant improvements in depression at six- and twelve-months post-intervention.

1.5.4.2 Rationale for guided self-help

The MS Society have a top ten list of research priorities. The list is the result of consultation with people with MS, their families, and healthcare professionals. Listed in their priorities is research on "How can people with MS be best supported to self-manage their condition?" (MS Society, 2018b). Guided self-help would allow people with MS to use self-management for their condition. Additionally, research on the effectiveness of interventions for self-management of the condition contributes to the MS Society's research priorities.

NICE (2017), recommend self-help interventions as a first line intervention. Using guided self-help makes access to treatment largely accessible to a large number of individuals with potentially small costs to the NHS. Indeed, research on guided self-help for people with psychological distress has promising indications despite some limitations in the quality of assessed studies. Unfortunately, the acceptability of self-help interventions by individuals is unclear. In a systematic review where 31 studies were identified none of the studies assessed individual's acceptability of self-help interventions (Lewis et al., 2012). However, when individuals engage, the effectiveness for the treatment of depression and attrition rates are comparable to face-to-face interventions (Cuijpers et al., 2010).

1.6 Behavioural activation

Behavioural activation is a type of psychological therapy that encourages individuals with depression to engage in activities they have been avoiding in which individuals define goals and activity schedules (Veale, 2008).

Behavioural activation is a structured psychotherapeutic approach which aims to (a) increase engagement in activities associated with pleasure or mastery, (b) decrease engagement in activities that maintain depression, and (c) problem solve barriers limiting access to reward or maintain aversive control (Dimidjian et al., 2011). Behavioural activation is a relatively simple, easy to understand, intervention that does not require a highly trained therapist or complex skills from the patient (Lejuez et al., 2011), and may be suitable for individuals with cognitive and physical difficulties. Behavioural activation is based on the behavioural model of depression (Lewinsohn & Shaffer, 1971). Specifically, that depression is a result of reduced positive reinforcement, particularly in social relationships. Social relationships are considered important by Lewinsohn and Shaffer (1971) in preventing and overcoming depression. Behavioural activation aims to reduce depressive symptoms by implementing a schedule of positive reinforcement by altering an individual's behaviour and/or their environment. As, in certain environmental contexts, behaviours that reduce depression will continue to occur through reinforcement and those that increase depression will decrease over time (Roane et al., 2016).

The origin of behavioural activation can be seen in Lewinsohn and Libet's (1972) seminal paper on pleasant events scheduling, several treatments developed in the 1970s (Kanter, Manos, et al., 2010), and its use as a component of cognitive therapy (Beck et al., 1979).

Lewinsohn et al. (1976) developed an intervention manual based on a collection of earlier intervention studies. The manual outlines that individuals should engage in activity scheduling to overcome deficits in environmental positive reinforcement and social skills to overcome behavioural deficits in acquiring and maintaining reinforcement. A number of interventions were evaluated based on Lewinsohn et al.'s (1976) manual. At the same time, alternative models were being developed based on varying behavioural models. For example, one approach emphasised training in behavioural, interpersonal, and cognitive skills (McLean, 1976). One approach used self-control therapy which utilised Lewinsohn's interventions and included techniques from Kanfer's (1970) behavioural model of self-control such as cognitive techniques (Rehm, 1977). Despite empirical support building throughout the 1970s, the utilisation of behavioural approaches declined in the late 1970s and early 1980s (Kanter, Manos, et al., 2010). The changes were in part the result of a study that indicated that cognitive therapy was superior to behavioural interventions (Shaw, 1977) and a second study that completed a component analysis that showed no difference in the effectiveness of activity scheduling, cognitive techniques, or skills training (Zeiss et al., 1979). Following the studies, Lewinsohn began integrating cognitive and behavioural techniques (Lewinsohn et al., 1986) and the integration of cognitive and behavioural approaches gained momentum which led to CBT being the most researched form of psychotherapy (David et al., 2018).

A later component analysis of cognitive therapy also found no difference in the effectiveness between cognitive and behavioural approaches (Jacobson et al., 1996). The design of the study meant that cognitive techniques were added to behavioural techniques which led to the conclusion that adding cognitive techniques did not improve outcomes. Further, Jacobson concluded that based on the equal

efficacy but improved efficiency and ease of training that behavioural activation techniques were superior to cognitive techniques.

1.6.1 Theoretical underpinnings of behavioural activation

Ferster (1973) posited that depression is characterised by an increase in certain behaviours and a decrease in other types. Ferster stated that an increase in escape and avoidance behaviours of depressed individuals meant that people receive fewer rewards from their activities. The decrease in reward is the result of individuals not engaging in productive activities often enough, which reduces the effectiveness of the reinforcement of those activities. Further, depressed individuals engage in behaviours to escape aversive feelings which prevented positively reinforced behaviour. Avoiding aversive feelings results in depressed individuals' behaviour being negatively reinforced rather than positively reinforced. Specifically, behaviour serves to reduce aversive states instead of allowing an individual to engage in their environment where behaviour is naturally rewarded and positively reinforced.

Lewinsohn (1974) used behavioural theory to posit that depression is a function of low rates of response-contingent positive reinforcement and inadequate social skill. Behavioural activation manuals aim to decrease behaviours that sustain or exacerbate depression by promoting counteracting behaviours (Martell et al., 2001). Behaviours are counteracted by using techniques such as activity monitoring and scheduling (Jacobson et al., 1996), which address environmental deficits in positive reinforcement and difficulties in acquiring and maintaining reinforcement (Kanter, Santiago-Rivera, et al., 2010).

Response-contingent is defined as "reinforcement that is dependent on an individual's actions" (Martell et al., 2010, p.7). For example, if a

person attempts to speak to a friend to arrange to meet and the friend ignores the attempt (i.e., does not provide response-contingent reinforcement) or rebukes the invite as "clingy" (i.e., punishes), eventually the individual will cease attempts to converse and they will feel sad about the friendship. Over time conversation behaviours may extinguish, reducing positive reinforcement and behaviours that typically result in reward which can maintain depression.

Reduced rates of response-contingent positive reinforcement not only occur in upsetting or negative events. Lewinsohn (1974) explained that events such as job promotions can lead to a loss of social reinforcement because individuals can lose peers in the transition to management.

As described earlier, operant conditioning describes the maintenance of depression. The efficacy of behavioural activation supports the operant conditioning account of depression (Veale, 2008). As, behavioural activation interventions promote engagement in avoided activities and a functional analysis of avoidance-based cognitive processes. By raising an individual's level of activity whilst simultaneously reducing avoidant behaviours there is increased opportunity for environmental reinforcement and a greater engagement in a range of behaviours.

As highlighted, when compared to cognitive interventions, behavioural activation was found to be as effective which provides support that the behavioural theory of depression is comprehensive enough to inform the development of treatments (Ekers et al., 2011). Yet many approaches include a functional analysis of the cognitive factors that maintain avoidant behaviour (Veale, 2008), meaning that using behavioural accounts in isolation may be reductionist.

Indeed, whilst depressed cognitions are considered to be behaviours associated with dysphoria due to a lack of response-contingent reinforcement, operant conditioning fails to account for individuals without depression experiencing similar thoughts as those reported by individuals with depression. Contrastingly, cognitive theorists posit that cognitions have a causal role in depression and are not merely a product of depression (Beck, 1967; Beck et al., 1979).

Whilst it has been argued that behavioural theory fails to account for common group factors of depression, behavioural activation was developed to be a flexible intervention that is tailored to the individual receiving treatment. The behavioural activation model is not intended to assume that specific classes of behaviours are reinforcing for an individual. Instead, behavioural activation uses functional analysis to increase behaviours with the highest potential for an individual to interact with their environment that provides positively reinforcing antidepressant behaviour (Martell et al., 2010).

1.6.2 Behavioural activation components

Kanter, Manos, et al. (2010) reviewed three meta-analyses to identify the component techniques used in behavioural activation studies. Of the 32 identified trials six behavioural activation manuals were frequently referenced (Beck et al., 1979; Gallagher et al., 1981; Lejuez et al., 2001; Martell et al., 2001; McLean, 1976; Rehm, 1977). The six manuals and the earlier manual, Lewinsohn et al. (1976), shared several components. All seven manuals include activity monitoring, and activity scheduling; five manuals include skills training, contingency management, and procedures targeting verbal behaviour; three manuals include values and goals assessment; two manuals include relaxation; and one manual includes procedures targeting avoidance. In addition to these eight overarching categories of

behavioural activation interventions, a variety of ancillary techniques were also identified. The ancillary techniques include procedures considered common to all psychotherapies such as developing therapeutic rapport and a treatment rationale (Kanter, Manos, et al., 2010). Additional techniques included homework, setting agendas, and relapse prevention.

1.6.2.1 Activity monitoring

Activity monitoring is used to provide baseline information of an individual's activity levels and mood to inform future activation assignments. Activity monitoring is also used to support the rationale of behavioural activation to clients by demonstrating a relationship between activity levels and mood. An activity chart can be used to identify an individual's current behaviours that they enjoy and unhelpful behaviours. Further, activity charts can be used to highlight avoidance behaviours, experiences of mastery and pleasure, restriction of activity, and consistency with values (Martell et al., 2001). Activity charts are used to reduce and replace activities that maintain an individual's low mood (Dimidjian et al., 2011; Dimidjian et al., 2006).

Initially, activity monitoring was not envisioned as an intervention to change behaviour itself, instead, it was conceptualised as a necessary precursor to change. However, it is reported that the process of activity monitoring positively impacts outcomes as a standalone intervention and has reduced smoking behaviour (McFall, 1970), ruminating (Frederiksen, 1975), and binge eating (Latner & Wilson, 2002). Yet, combining activity scheduling with activity monitoring is more effective than monitoring alone (Graf, 1977).

1.6.2.2 Values and goals assessment

Many psychotherapies begin with an assessment of an individual's goals for therapy. Some variants of behavioural activation also include an assessment of goals and values to inform activation assignments. For example, Lejuez et al. (2001) assess an individual's values in a simplified form of Acceptance and Commitment Therapy (Hayes et al., 1999) and the values are used to develop specific goals for activation.

Some argue that values are an issue of cognition and not behaviour (Kanter, Manos, et al., 2010), however, behavioural theory views values functionally as reinforcers. Specifically, that the process of identifying and verbalising values orientates an individual toward ideographical defined positive reinforcers (Bonow & Follette, 2009). For example, the value of "being a good husband" is not a specific behaviour, however, it suggests a number of behaviours that can be associated with "being a good husband" which could be reinforcing if engaged in. Further, it is possible that the process of stating a value may serve as a reinforcing consequence for value associated behaviour. For example, saying "I am a good husband" may solidify certain behaviours as reinforcing as they are verbally evaluated to be consistent with being a good husband, even in the absence of environmental support for the behaviour (Kanter, Manos, et al., 2010). The use of values may motivate and sustain behaviour when environmental reinforcers are not expected to be immediately present (Kanter et al., 2009). Using values-based interventions may be beneficial in circumstances where activation behaviours result in immediate aversive states that could result in future avoidance in the absence of immediate reinforcement (Plumb et al., 2009). Therefore, if values are strongly held by an individual, as verbally-derived reinforcement, the value may maintain behaviour in the face of

competing, aversive consequences that would extinguish behaviour (Kanter et al., 2009). In individuals with secondary progressive MS values also provide an opportunity to continue to access environmental reinforcement when increasing physical disability may remove the opportunity for engagement with activation events.

1.6.2.3 Activity scheduling

The purpose of activity scheduling is for an individual to increase contact with environmental positive reinforcement. Individuals and their clinician usually collaborate to set homework tasks to engage in activities to increase contact with positively reinforcing behaviours. Early interventions focused on pleasant events scheduling. More recently, the scheduling of activities has moved to encouraging individuals to focus on pleasure and mastery ratings of completed activities (Beck et al., 1979). Many approaches also grade task assignment; using hierarchy to engage in activities that individuals feel most able to expose themselves to, based on their mood and perceived resources. Activity scheduling is used as stimulus control to produce prompts in the environment to improve behaviour or remove problematic behaviour.

1.6.2.4 Skills training

Skills training is a label for a collection of interventions including social skills such as assertiveness, communication, or interpersonal skills, and non-social skills such as problem solving (Kanter, Manos, et al., 2010). Skills training has been used when individuals do not know how to engage in effective behaviour that results in environmental reinforcement. It was thought that depressed individuals may lack the social skills to engage in activities, which ultimately may mean that scheduling activities will fail because the individual is not able to obtain

or maintain contact with reinforcing behaviours (Kanter, Manos, et al., 2010). Techniques such as role plays, and modelling are employed in an attempt to develop skills within the therapy room and then test the acquired learning as part of the homework task in the individual's environment.

1.6.2.5 Relaxation

Relaxation techniques have been integrated into some behavioural activation treatment manuals. Relaxation techniques have been used to target sleep difficulties and to enhance the experience of enjoyable activities (Kanter, Manos, et al., 2010). It has been suggested that the use of relaxation techniques is beneficial for the treatment of depression due to the overlapping symptoms between depression and anxiety (Morgan & Jorm, 2008).

1.6.2.6 Contingency management

Contingency management aims to address situations where efforts toward engaging in helpful behaviour is punished or not rewarded by the environment, or, when unhelpful behaviours are maintained by positive or negative environmental reinforcement (Kanter, Manos, et al., 2010). Contingency management is used when immediate environmental reinforcement is not available. Contingency management is used by using self-reinforcement on targeted positive behaviours. The aim is that by taking control of reinforcement and rewarding at close temporal proximity to the target behaviour that the intended behaviour will increase (Petry, 2011).

1.6.2.7 Procedures targeting verbal behaviour

Despite the critique made by many that behavioural interventions fail to address cognitive mediators of depression and that cognitive content is not addressed, a number of behavioural interventions specifically

target verbal behaviour. For example, Lewinsohn (1974) addressed negative cognitive content by discussion and other behavioural activation interventions target covert verbal behaviour. Behavioural interventions differ from cognitive approaches as they do not aim to restructure cognitions, but, focus on the frequency. By focusing on the frequency individuals aim to decrease the frequency of negative covert verbal behaviours and increase the frequency of positive covert verbal behaviours (Kanter, Manos, et al., 2010). Early interventions used thought suppression, rehearsing positive thoughts, and substituting negative thoughts with positive thoughts (McLean, 1976). More recently, behaviourists have begun to view thoughts contextually and consider thought suppression or replacement as futile (Kanter, Manos, et al., 2010). Rather than reducing the frequency of negative verbal behaviour a functional approach is used to explore the context in which negative thought behaviour occurs and the consequences that maintain the behaviour (Martell et al., 2001).

1.6.2.8 Procedures targeting avoidance

Only one of the behavioural activation manuals uses procedures to target avoidance (Martell et al., 2001). The process was developed using the behavioural theory of depression and the behavioural theory of anxiety. Behavioural techniques for the treatment of depression focused on deficits in positive reinforcement, whereas, the behavioural theory of anxiety focused on excessive negative reinforcement. Yet, it was posited that they were interrelated (Ferster, 1973) and techniques were developed to support individuals to identify avoidant behaviour and activate target behaviours in the face of competing avoidance tendencies (Martell et al., 2001).

1.6.3 Research on behavioural activation

Over the years a number of meta-analyses have been conducted and demonstrated the efficacy of behavioural activation (Cuijpers et al., 2007; Ekers et al., 2008; Mazzucchelli et al., 2009). In the Ekers et al. (2008) meta-analysis 17 randomised-controlled trials with 1109 participants were identified. Post-treatment depression scores were superior to controls (standardised mean difference [SMD] -0.70, 95% CI -1.00 to 0.39), brief psychotherapy (SMD -0.56, 95% CI -1.0 to -0.12), supportive therapy (SMD -0.75, 95% CI -1.37 to -0.14), and equal to CBT (SMD 0.08, 95% CI -0.14 to 0.30). The Mazzucchelli et al. (2009) meta-analysis identified 34 randomised-controlled trials with 2055 participants. The pooled effect size for post-treatment depression when compared to controls was significant with an effect size of 0.78 (95% CI 0.58 to 0.97) favouring intervention; using 16 studies and 453 participants. Again, no significant difference was found between behavioural activation and cognitive therapy.

Behavioural activation was evaluated against the standards for the promotion and dissemination of psychological procedures, the authors concluded that behavioural activation should be designated a well-established and empirically validated treatment (Mazzucchelli et al., 2009; Task Force on Promotion and Dissemination of Psychological Procedures, 1995).

In non-neurological populations, the behavioural activation component of CBT is as effective alone, compared to when used in combination with cognitive aspects (Jacobson et al., 1996) – and has been found to be as effective as antidepressant medication (Dimidjian et al., 2006). Both behavioural activation and antidepressant medication were significantly more effective than cognitive therapy (Dimidjian et al.,

2006). This demonstrates the potential use of behavioural activation as a parsimonious intervention. Comparable therapies are important as engagement in CBT may be difficult for people with neurological conditions because they can experience fatigue and cognitive difficulties (Motl et al., 2009), which may limit their effectiveness. Behavioural activation may represent a less burdensome intervention versus CBT.

A meta-analysis of activity scheduling (a type of behavioural activation) interventions for the treatment of depression found a pooled effect size of 0.87, favouring activity scheduling over waitlist or placebo controls or alternative psychological therapies (95% CI: 0.60~1.15) and heterogeneity was low (Cuijpers et al., 2007). The authors conclude that future research using behavioural activation in difficult populations is needed. Specifically, when considering the advantages of activity scheduling: a simple, easy to understand treatment, which does not require complex skills from therapists, it would be beneficial to examine if activity scheduling can be applied in difficult populations which cannot be treated with complex interventions. Also, whether activity scheduling could replace more complex psychological interventions, which require greater intellectual capabilities from patients (Cuijpers et al., 2007).

In an updated meta-analysis of the effectiveness of behavioural activation for depression by Ekers et al. (2014) 26 randomised-controlled trials, with 1524 participants, showed behavioural activation was superior to controls for post-treatment scores on depression (SMD −0.74 CI −0.91 to −0.56) and medication (SMD −0.42 CI −0.83 to -0.00). Study quality was low in most of the studies and the authors reported that follow-up periods were short.

Behavioural activation is also considered cost-effective (Richards et al., 2016). In individuals without neurological conditions behavioural activation was delivered by junior mental health workers, who received less costly or intensive training than psychologists, with effectiveness as equal as CBT (Richards et al., 2016). Behavioural activation represents a parsimonious alternative to CBT which may increase individual's self-efficacy, reduce functional disability, and increase self-management reducing overall costs.

1.6.4 Behavioural activation and multiple sclerosis

There are no published trials for the use of behavioural activation for individuals with MS as evidenced by a recent systematic review investigating behavioural activation for depression in individuals with neurological conditions (Oates et al., 2019). However, the authors of the review identified ten studies that used behavioural activation for the treatment of depression in neurological conditions including dementia (*n*=4), stroke (*n*=3), epilepsy (*n*=1), brain injury (*n*=1) and Parkinson's disease (*n*=1). Seven of the ten studies were randomised-controlled trials but none of the studies compared behavioural activation to an alternative psychotherapy. Eight of the ten studies reported a reduction in depression post-treatment favouring behavioural activation with effect size ranging from small to large (*d* = 0.24–1.7). However, the methodological quality of the studies varied with higher quality studies needed. Many of the included studies had small sample sizes and level of disability not often reported. Some studies detailed adaptations that were made to support the delivery of the intervention such as using the telephone to conduct sessions, delivering interventions directly to carers, or giving psychoeducation to carers. The reported efficacy of behavioural activation in individuals with neurological conditions is comparable to pooled effect sizes reported in meta-analyses in populations without neurological

conditions. However, the results should be treated with caution due to the sub-optimal quality of the included studies. None of the studies were able to demonstrate mediators of change and future studies would benefit from improved quality.

1.6.5 Brief Behavioural Activation Treatment for Depression: Revised treatment manual (BATD-R)

Following the component analysis of cognitive therapy by Jacobson et al. (1996), Lejuez et al. (2001) developed the Brief Behavioural Activation Treatment for Depression (BATD) manual, the manual was described as such because it used a fewer number of sessions than Jacobson et al.'s (1996) manual which used 20 sessions. The manual used behavioural theory to target contextual factors impacting behaviour and matching law (Herrnstein, 1970). Matching law suggests that when multiple schedules of reinforcement are available at the same time for different behaviours, individual's behaviour typically follows the proportions of reinforcement provided by different response options, whilst also describing conditions where behaviour may deviate in allocation due to over or under matching. In other words, depression is a function of both decreased reinforcement for non-depressive behaviours and increased reinforcement for depressive behaviours (Kanter, Manos, et al., 2010). The BATD is a 12-session protocol and includes activity monitoring, goals and values assessment, activity scheduling, and contingency management. The manual was used in a number of trials and found improved depressive symptoms (Hopko et al., 2003).

The manual was revised ten years after initial publication. The BATD-R had modifications that simplified and clarified treatment elements and procedures. The modifications included: (a) greater emphasis on treatment rationale, including therapeutic alliance; (b) greater clarity

regarding life areas, values, and activities; (c) simplified (and fewer) treatment forms; (d) enhanced procedural details, including troubleshooting and concept reviews; and (e) availability of a modified daily monitoring form to accommodate low literacy patients (Lejuez et al., 2011). The manual was streamlined and includes five unique sessions and five additional sessions to allow for concept review. The BATD-R has been modified to include fewer sessions and showed significant reductions in depression using six to eight sessions (Daughters et al., 2008; MacPherson et al., 2010) and benefits have been seen in a single session (Gawrysiak et al., 2009).

1.7 Rationale for behavioural activation in secondary progressive multiple sclerosis

NICE recommended that research should investigate behavioural activation in people who have chronic illness (National Collaborating Centre for Mental Health & National Institute for Health Clinical Excellence, 2010). When considering that outcomes in the general population have been as comparable to CBT, in an increasingly strained national healthcare service, identifying, viable cost-effective interventions is becoming increasingly necessary. Further, if individuals with neurological conditions, such as MS, are experiencing increasing fatigue, worsening symptoms, and difficulties accessing therapies, behavioural activation may offer the most accessible intervention.

For people with neurological conditions, such as MS, depression may be a result of declining physical health which may make it increasingly difficult to engage in activities that individuals previously found enjoyable or positively reinforcing. Behavioural activation aims to support individuals to identify and increase their access to positive reinforcement within their environment and reduce sources of negative reinforcement. As behavioural activation focuses on increasing

rewarding activities and not changing cognitions, behavioural activation may be an acceptable intervention for people with secondary progressive MS.

Behavioural activation is a parsimonious intervention. Jacobson et al. (1996) argued that behavioural activation alone can be used as a streamlined intervention, which can achieve maximal impact for minimal burden. When considering that depression is a problem for people with secondary progressive MS and that we do not know the best way to intervene, using values as a means for identifying activities for contingent reinforcement may be of benefit. There is an existing evidence-base for the use of the BATD-R and its adaptability more broadly. However, evidence is limited in its examination of individual-level moderators and mediators of change, which is important for refining our theoretical understanding of therapeutic mechanisms and when tailoring/implementing such interventions with people with MS in practice.

The inclusion of values within the treatment manual may be important for people with secondary progressive MS, due to their on-going increasing difficulties. By exploring activities that people with secondary progressive MS enjoy or previously enjoyed an exploration of the components of joy can be made. New activities can then be sought that contain the same components. Lejuez et al. (2011) suggest by understanding an individual's values associated with an activity can provide positive reinforcement over time, due to activities being linked to values rather than being arbitrarily selected. This may increase their access to positive reinforcement in several areas of their lives, rather than fewer specific that may narrow the opportunities for success (Lejuez et al., 2011).

When considering the increased cost to services, impact on patient outcomes, and decreased quality of life it is important to understand the most appropriate treatments for depression. Adapting psychological therapies to better consider the interaction of co-morbid psychological and physical conditions may be more acceptable to people with neurological/physical health conditions (Cully et al., 2009).

Importantly, using behavioural activation may represent a simpler, cost-effective, intervention that represents a parsimonious option for psychotherapy. If outcomes on depression are equivalent to other psychotherapies but represent a smaller dose of psychotherapy services may be able to increase their efficiency and be able to support a greater number of individuals.

2. Extended methods

2.1 Epistemological position

The aims of the study lend themselves to a critical realist framework. Critical realism posits that a world exists independent of an individual's understanding, language, and beliefs, but subjective interpretations impact the way it is experienced (Edwards et al., 2014). In the study, individuals' experiences, history, beliefs, and the context in which they live impact their expectations; however, there is an objective reality that exists beyond the individual that will have an influence on the findings. Outhwaite (1987) highlights that science is not simply a deductive process of detecting causal relationships, but one that seeks to investigate wider contextual factors that work together to influence events.

2.2 Design

The Medical Research Council framework for the development and evaluation of complex interventions (Craig et al., 2008) state interventions should be developed systematically, using available evidence and theory. Interventions should be tested using a phased approach, beginning with a series of pilot studies targeting uncertainties in the design. The aims of the study were closely aligned with the 'development' phase of the framework and were achieved using mixed-methods.

One method of investigating person-to-person variability and mechanisms of change in clinical interventions, is the single-case experimental design (Craig et al., 2008). Where randomised-controlled trials aim to demonstrate change in outcomes between two-time points, single-case experimental designs aim to understand whether

intervention processes are accountable for change (Craig et al., 2008). By exploring mechanisms through which interventions introduce change, researchers can investigate theoretical mediators of that change (Moore et al., 2015). This is crucial in understanding how these effects may be replicated in future research (Grant et al., 2013).

2.3 Ethics

Ethical approval for the study was granted by the East Midlands – Nottingham 2 ethics committee (ref: 19/EM/0013; ethical approval process can be seen in appendices B to D). Informed consent was obtained from each participant by the study researcher (LLO). The study was registered on ClinicalTrials.gov (reference NCT03935529).

2.3.1 Ethical considerations

The study was conducted in accordance with guidelines set out by the British Psychological Society (British Psychological Society, 2010) and adhered to the Good Clinical Practice guidelines (NIHR, 2016).

Individuals scoring highly on the Hospital Anxiety and Depression Scale (HADS) at screening were not excluded from the study but were encouraged to seek support from their GP. If a participant sought further support from their GP, the information was recorded within the participant's contact notes and discussed during analysis. Additionally, if the measures identified that a participant's mood was deteriorating during the intervention, the individual was advised to seek support from their GP.

The risks of suicide and suicidal intent are characteristic of the condition being investigated, for the purposes of the study they were classed as adverse events. Good Clinical Practice guidelines were

followed by monitoring mood changes through measures and contact. Where any risk was identified the risk protocol for Nottingham University Hospitals Trust was followed. Serious adverse events were documented and discussed with supervisors and the trust, in line with the HRA (2018) safety reporting guidelines.

During study design the researchers outlined that the study would be terminated if concerns were identified, following discussions with supervisors. Participants would be informed of the termination and provided with guidance on seeking further support, such as accessing their GP.

2.3.2 Consent

Informed written consent (Appendix E) was obtained from all participants. Individuals were given at least one week to decide if they would like to take part, before being contacted by the researcher. The field supervisor assessed the participant's capacity to consent and informed the researcher. If a participant was deemed to lose capacity to consent during the study, their involvement was terminated. Any concerns about capacity were discussed in research supervision. No plans were made to include individuals deemed to lack capacity due to the nature of the materials and intervention and the resulting engagement difficulties.

2.3.3 Participant withdrawal

Participants were informed of their right to withdraw from the study at any time point, without impact on their clinical care. Participants were invited to provide feedback, at interview, but were under no obligation to do so. Data collected up to the point of withdrawal was used within

the analysis, participants were informed of the analysis when consenting to take part.

2.3.4 Data management

In accordance with General Data Protection Regulations (The European Parliament & The Council of The European Union, 2016), research data, personal data, and the linking code were stored separately. Electronically stored data was password protected and encrypted, to ensure it was kept secure. Hard copies, such as consent forms, were kept in a locked filing cabinet at the university.

Upon study completion, personal data was stored for only as long as necessary, so that the researcher could provide a research summary. Research data will be kept in locked safe storage at the University of Lincoln, for a period of seven years, before it will be destroyed. Published results were anonymised and did not contain participant identifiable information.

2.3.5 Logistical considerations

Participants were remunerated with a £20 Amazon voucher. Gifting was in line with INVOLVE guidelines (NIHR, 2012). Whilst payment of participants can lead to concerns of result bias, this gift was made following the interview, and was a nominal thank you for participant's time.

If a participant failed to comply with the protocol, they were not excluded from the study, but they were asked if they were willing to take part in the interview to gather feasibility information.

2.4 Participants and recruitment

2.4.1 Sample size

A minimum of three replications, across successive cases, are required in single-case experimental design research, to meet standards for assumed intervention related change (Smith, 2012). Six participants are suggested for attrition (Smith, 2012).

2.4.2 Recruitment

Participants were recruited from Nottingham University Hospitals Trust, by the MS clinical care team, who provided participants with the study advertisement (Appendix F). Participants also self-referred, using information from study-related advertisements placed in the MS clinics, MS Society local branch newsletters and social media.

Within the Nottingham University Hospitals Trust MS clinic, 750 individuals with secondary progressive MS are regularly seen, on average 50 per month (Evangelou, personal communication, February 2018). Chwastiak et al. (2002) report depression prevalence in people with MS of 41.8%, with higher levels in people with more advanced disease. Therefore, we anticipated having an estimated population of 300 to sample from, of which 20 per month may be experiencing low mood.

Participants received a screening and information pack, containing a consent form (Appendix E), participant information sheet (Appendix G), and HADS (Appendix H). A telephone call from the researcher provided opportunity for further questions. If the participant did not meet the inclusion criterion (Table 6), they were excluded and provided an information sheet for managing emotions (Appendix I). Consenting participants' GP were sent a letter detailing their involvement in the study (Appendix J).

Table 6

Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Neurologist confirmed diagnosis of secondary progressive multiple sclerosis	People undergoing psychological therapy for a pre-existing mood problem.
English speaking	
Aged over 18 years	
Able and willing to give consent	
Have a telephone, access to the internet, and able to use a computer	
Score ≥ 8 on the HADS depression subscale	

Note. This table demonstrates the inclusion and exclusion criteria for the study.

[a] HADS; Hospital Anxiety and Depression Scale.

[b] Exclusion criteria was based on self-report.

2.4.3 Data collection and assessment

Demographic and clinical data were collected through self-report (Appendix K). The data allowed exploration of wider factors, beyond the intervention, to be included in any change analysis, and allowed for future replicability.

Feasibility data were collected in regard to recruitment, session attendance, attrition, questionnaire adherence, follow-up, additional support, interviews and acceptability, presented in Table 7.

Table 7

Feasibility questions

Feasibility information	How measured
Recruitment	Number of people given information by the multiple sclerosis team. Number of people screened using Hospital Anxiety and Depression Scale. Number of people meeting cut-off and consenting. Number of people not meeting cut-off on Hospital Anxiety and Depression Scale.
Session attendance	Data on overall percentage of sessions attended.
Attrition	Number of participants dropping out.
Questionnaire adherence	Record of missing data reported.
Follow-up	Number of participants completing follow-up measures.
Additional support	Number of participants directed to seek additional support from their GP.
Interviews	Number of participants completing the change interviews.
Acceptability of the materials, measures, and sessions	Qualitative feedback via interviews.

Note. This table demonstrates the feasibility questions answered in the study and how each element of feasibility information was measured.

2.5 Measures

This section describes screening, baseline, process, and outcome measures. Psychometric properties, method, and point of administration are reported in Table 8. As shown in Table 8, where possible, measures previously used in MS research were selected. The measures were used to screen, establish a baseline, investigate process, and outcomes.

2.5.1 Screening

The HADS (Zigmond & Snaith, 1983) was used to screen participants for inclusion (scoring ≥8 on the depression subscale).

2.5.2 Baseline

The Patient Health Questionnaire 2 (PHQ2; Kroenke et al., 2003; Appendix L) was used to establish a baseline. The PHQ2 was administered every-other-day, during the baseline phase, to establish a baseline for the primary outcome variable of interest (depression). As no higher frequency measure exists, questions were adapted to ask, 'over the last two days.' To overcome the impact of adapting the measure, outcome measures, such as the HADS, were used on a weekly basis. Internal consistency: α = .83 (Löwe et al., 2005). Sensitivity (82.9%) and specificity (90.0%) indicating a 38.4 positive predictive value (Kroenke et al., 2003). Sensitivity (99%) and specificity (87%) and positive predictive value (72%) have been investigated in a MS population.

2.5.3 Process measures

The Engaged Living Scale (ELS; Trompetter et al., 2013; Appendix M) was used to identify alignment to values, to allow us to understand the impact of values-based action. Internal consistency: α = .92. Subscales range from α = .62 to .89. Test–retest: r= .66 (p< .0001; Knirsch, 2015). Good construct validity has been reported (Trompetter et al., 2013).

The Behavioural Activation for Depression Scale Short Form (BADS-SF; Manos et al., 2011; Appendix N) was used to track participant engagement in behavioural activation. Good item characteristics and acceptable internal consistency are reported (Manos et al., 2011). Acceptable construct validity, and predictive validity (Kanter et al., 2012). The BADS-SF was used to track weekly changes in behaviours

that underlie depression and that are specifically targeted for change by behavioural activation.

2.5.4 Primary outcome

In line with study aims, the HADS was used to investigate change in depression.

2.5.5 Secondary outcomes

Levels of fatigue were investigated using the Modified Fatigue Impact Scale (MFSIS-SF; Vickrey et al., 1995; Appendix O). Internal consistency: $\alpha = .80$ (Vickrey et al., 1995). The questionnaire has high face validity due to use in MS research (Vickrey et al., 1995).

Changes to participant's quality of life, were investigated using the Short Form-12 version 2 (SF-12v2; Ware et al., 1996; Appendix P).

Table 8

Measures, psychometric properties, and delivery time points

Outcome measure	Aims to measure	Number of items, reflective period, direction of improvement, and score range	Reliability	Validity
HADS (Zigmond & Snaith, 1983)[1,2,3,4,5]	Anxiety and depression	14 items Over the last week Decrease Subscale range 0 - 21	Anxiety subscale internal consistency: α = .83 (mean) Depression subscale internal consistency: α = .82 (mean) (Bjelland et al., 2002)	Sensitivity: 90%, Specificity: 87% (Hind et al., 2016). High sensitivity and specificity have been reported versus clinical interview and other measures, in people with multiple sclerosis (Honarmand & Feinstein, 2009). In 2016, a systematic review comparing mood measures used with people with multiple sclerosis Hind et al. (2016). The authors reported the HADS had a sensitivity of 90%, which was the highest of the compared mood measures in the review

Outcome measure	Aims to measure	Number of items, reflective period, direction of improvement, and score range	Reliability	Validity
SF-12v2 (Ware et al., 1996)[2,3,4]	Quality of life	12 items Over the last four weeks Increase Range 0 - 100	Internal consistency α = >.8 (Cheak-Zamora, Wyrwich, & McBride, 2009)	The questionnaire was populated from the full version which has high face validity due to use in multiple sclerosis research (Vickrey et al., 1995). Additionally, the SF-12v2 has been used within multiple sclerosis populations
MFIS (Vickrey et al., 1995)[2,3,4]	Fatigue	5 items Over the last four weeks Decrease Range 0-20	Internal consistency: α = .80 (Vickrey et al., 1995)	The questionnaire has high face validity due to use in multiple sclerosis research (Vickrey et al., 1995)
ELS (Trompetter et al., 2013)[2,3,4,5]	Values	16 items Non-stated Increase	Internal consistency: α = .91 (Trompetter et al., 2013). Subscales range from α = .62 to .89	Good construct validity has been reported (Trompetter et al., 2013)

Outcome measure	Aims to measure	Number of items, reflective period, direction of improvement, and score range	Reliability	Validity
		Total score range 16 – 80 Valued living range 10 – 50 Life fulfilment range 6 - 30	Test–retest: r= .66 (p< .0001) (Knirsch, 2015)	
PHQ2 (Kroenke et al., 2003)[6]	Depression	2 items Over the last two weeks Decrease Range 0-6	Internal consistency: α = .83 (Löwe et al., 2005)	Sensitivity (82.9%) and Specificity (90.0%) indicating a 38.4 positive predictive value (Kroenke et al., 2003). Sensitivity (99%) and specificity (87%) and positive predictive value (72%) have been investigated in a multiple sclerosis population

Outcome measure	Aims to measure	Number of items, reflective period, direction of improvement, and score range	Reliability	Validity
BADS-SF (Manos et al., 2011) [2,3,4,5,6]	Activation	9 items Over the last week Increase Range 0 - 54	Internal consistency: α = .82 Good item characteristics and acceptable internal consistency are reported (Manos et al., 2011)	Acceptable construct validity, and predictive validity (Kanter et al., 2012)

Note. The online database was facilitated by a software known as Qualtrics. The software sends a link and a reminder to participants to complete questionnaires via their phone or computer.

[a] The reflective period represents how questions are phrased, such as "how often over the last week, have you…"
[b] HADS, The Hospital Anxiety and Depression Scale; SF-12v2, Short Form-12 version 2; MFIS-SF, Modified Fatigue Impact Scale-Short Form; ELS, Engaged Living Scale; PHQ2, Patient Health Questionnaire 2; BADS-SF, Behavioural Activation for Depression Scale Short Form.
[c] Time point administered: 1, Screening; 2, Pre-intervention; 3, Mid-intervention; 4, Post-intervention; 5, Weekly; 6, every-other-day during baseline

2.6 Design method

2.6.1 Intervention manual

The BATD-R was adapted for supported self-help use for people with secondary progressive MS (author permission, Appendix Q). The supported self-help format involved participants receiving five sessions delivered by the researcher.

- The script was condensed into a five-session format using the five core sessions (Appendix R).
- A resource pack for participants, including psychoeducation materials (depression, behavioural activation, values) was organised (Appendix S).
- A session fidelity framework was identified (Appendix T).

In addition, the protocol was updated to use a combination of face-to-face and telephone/internet calls. The duration of sessions was changed and included an up to two-hour initial session followed by sessions lasting up to one-hour. The existing session material was altered to improve its accessibility, such as removing cancer references.

2.6.2 Adaptations

The BATD-R manual consists of ten sessions, consisting of five unique and five additional sessions; for concept review and post-treatment planning. The manual has been previously modified to include fewer sessions (six-to-eight) and the abbreviated format significantly reduced depression in participants (Daughters et al., 2008; MacPherson et al., 2010). Indeed, beneficial effects have been reported from receiving one or two sessions (Armento et al., 2012; Gawrysiak et al., 2009). Therefore, the intervention content was focused into five, fortnightly sessions, using the unique sessions, allowing time to engage in activities. It was considered that fewer sessions could be beneficial,

as demonstrating change in a fewer number of sessions would have clinically relevant implications by representing a lesser demand on resources, whilst promoting self-management for people with MS. Further, it would be comparable to existing services such as IAPT.

As the manual is written in American English, the manual and materials, including values identification worksheets and diaries were adapted.

As people with secondary progressive MS experience physical difficulties, which can impact their ability to attend appointments, internet-video communication (e.g., Skype) and telephone calls were used to conduct sessions.

2.6.3 Acceptability of the manual

The adapted materials were checked for acceptability, against the original manual, in a project team meeting. Materials were sent to an existing patient and public involvement (PPI) panel, consisting of people with MS, some of whom have secondary progressive MS, who were available to consult on research projects. PPI can help define what is acceptable to participants and provide insight into potential barriers to engagement (National Institute for Health Research, 2014; NIHR). Feedback was requested on the structure and duration of sessions and suitability of materials. As these activities are conducted under the auspices of PPI, Health Research Authority guidance suggest ethical approval was not required (Health Research Authority, 2017).

2.6.4 Intervention

The delivery of the intervention was facilitated by the researcher. To investigate changes to mood and whether/how behavioural activation processes can account for any observed change, a multiple single-case experimental design (MSCED) was used.

2.6.5 MSCED

Craig et al. (2008) state that in the development and evaluation of interventions, it is important to first understand whether the intervention is effective in everyday practice and second, to understand how the intervention works. A feasibility randomised-controlled trial can assess the average effect of an intervention within a group. However, this design is unable to investigate theoretically predicted mediators of change between and within individuals, needed to explore how an intervention works (Craig et al., 2008).

In comparison, MSCEDs investigate the effectiveness of psychological interventions, by examining behaviour and interpersonal processes (Smith, 2012). Single-case experimental designs are an approach to investigate treatment efficacy (Rassafiani & Sahaf, 2010). Therefore, using MSCED leant itself to the study aims. MSCEDs are experimental by design, capable of providing a rigorous, methodologically sound method of evaluation (Smith, 2012). Manipulating the independent variable, by implementing and removing it at selected time-points, allows researchers to examine causal effects and test hypothesised contingencies (Barlow et al., 2008). Single-case experimental designs differ from comparative group studies by focusing on individual differences, rather than group differences. Using MSCED allows researchers to examine cause and effect if any change is identified in participants (Backman et al., 1997). The method used in MSCED reduces the potential that confounding variables are attributed to change on the dependent variable, because, researchers are able to use time series data to investigate association of change (Rassafiani & Sahaf, 2010). Rich data sets in MSCEDs are beneficial for investigating the aims of the study because it allowed exploration of the impact of behavioural change.

Typically, an ABA design would see participants go from no-intervention (A), intervention (B), back to no-intervention. However, as the intervention involved learning, it cannot be unlearned, therefore the effect of the intervention (or component phases) cannot be readily taken away. The study used an AB design, where A was baseline and B was the intervention.

Using an AB design each participant became their own control, as prior to intervention, we understood their usual responding for the target variable. Data were then tested for changes in the target variable (over-and-above the usual responding) once the intervention was introduced. Therefore, any behaviour change during the treatment phase can be attributed to the intervention. To establish a stable baseline, baselines must have at least three data points, to sufficiently establish baseline trend, level, and stability, against which to test intervention-phase changes (Smith, 2012).

Randomised controlled-trials (RCT) are frequently used to examine the efficacy of interventions. However, RCTs do not examine individual outcomes meaning that participants who are in a group that demonstrated change but encountered opposite effects are not understood (Davies et al., 2007). By investigating individuals, MSCEDs provide an important role in clinical psychology as they provide practitioners with evidenced-based clinical practice (Bloom et al., 2003). As participants receive repeated measurement on target variables, MSCED examines both whether change occurs, but also whether the change is significant, stable, and what caused the change (Davies et al., 2007).

2.6.6 Interviews

Post-intervention, one-to-one interviews were conducted to inform feasibility aims (acceptability of the intervention and research

procedures). Interviews were conducted by CM (Trainee Clinical Psychologist) who was not otherwise involved in the study. All interviews were audio recorded. The interview schedule (Appendix U) was based on Elliott and Timulak's (2005) change interview. Participants provided feedback about their experiences of the study to elicit an understanding of their lifestyle during the intervention, to consider any potential extraneous variables that may impact the findings and what participants attribute change to. The framework has been used in psychological intervention studies to provide qualitative information on positive and negative changes. Further, the framework asks participants to theorise which, if any, aspect of the intervention they would attribute to changes (Castonguay, 2011; Clarke et al., 2004; Klein & Elliott, 2006). This allowed for triangulation of the results; using outcome data and verbal feedback (Morse, 1991).

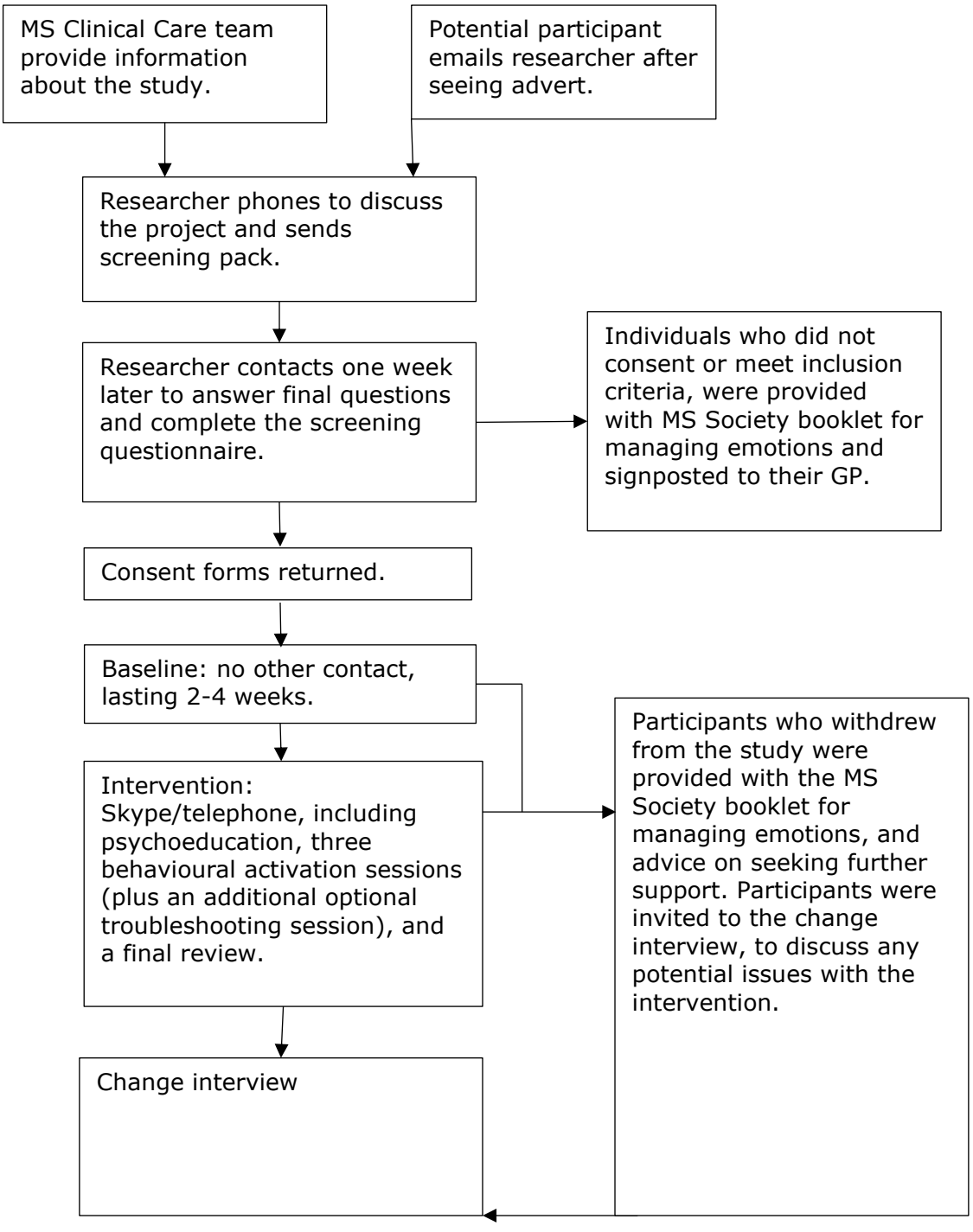
Based on guidelines (Srivastava & Thomson, 2009) change interview data were evaluated by considering contextual, diagnostic, evaluative, and strategic categories in terms of the following questions: was any positive or negative impact described, what was the context surrounding the intervention like and could change be attributed to environmental factors, what factors underlie the participants perceptions, what barriers in therapy existed, and how can the process be improved?

2.7 Intervention/procedure

This section outlines the participant journey. The procedure flowchart is reported in Figure 6.

Figure 6

Procedure flow chart



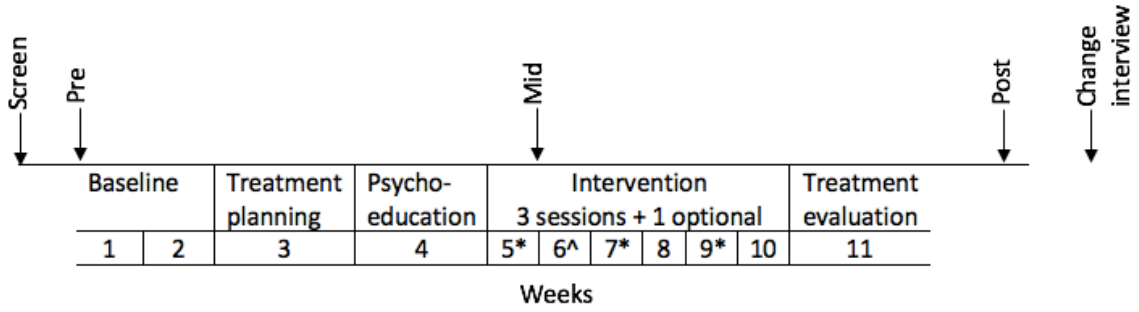
2.7.1 Baseline

Following recruitment, participants were sent instructions for installing video communication software (Skype). The researcher contacted the participant to complete pre-intervention measures and collect

demographic and clinical information. Following the contact, participants completed the PHQ2 every-other-day to establish a baseline. Participants completed measures using Qualtrics (a data management service). Qualtrics allowed participants to upload their responses to an online database using their phone or computer. Intervention and measures timeline are reported in Figure 7.

Figure 7

Intervention and measures timeline



* Denotes intervention session
^ Denotes optional session
During baseline the PHQ2 and Behavioural Activation for Depression Scale Short Form will be administered every-other-day
Screen: Hospital Anxiety and Depression Scale
Pre and Post: Hospital Anxiety and Depression Scale, Health Status Questionnaire, Modified Fatigue Impact Scale, Engaged Living Scale, Behavioural Activation for Depression Scale Short Form.
Weekly: Hospital Anxiety and Depression Scale, Engaged Living Scale, Behavioural Activation for Depression Scale Short Form.
Mid: Health Status Questionnaire, Modified Fatigue Impact Scale.

2.7.2 Intervention

An overview of the sessions delivered by the researcher can be seen in Table 9. The contacts were guided by the five unique sessions of the BATD-R, which were:

Treatment planning

Participants received a single face-to-face session at their home, lasting at least one-hour up to a maximum of two-hours.

Psychoeducation and behavioural activation

Participants received a single psychoeducation session, followed by three, fortnightly, behavioural activation sessions. In addition, participants were offered an optional support session for troubleshooting. Participants opted-in to the session, by responding to a question via Qualtrics. Sessions lasted up to one-hour and contact was made using internet video software or telephone.

Treatment evaluation

Participants received a review session lasting up to one-hour, contact was made using internet video software or telephone.

2.7.3 Post-intervention

Participants were contacted by a fellow Trainee Clinical Psychologist to take part in a 30-minute, one-to-one, audio recorded phone interview.

Table 9

Session plan outlining content, delivery method, homework, and overview

Session/week	Content	Delivery method	Homework	Overview
Treatment planning (week 3)	Outline the role of the researcher. History taking. Participant's presenting difficulties. Identifying behaviour change. Discussion of depression. Introduction to treatment rationale, including a discussion on pleasure and mastery ratings.	Face-to-face	Complete daily monitoring form	The face-to-face session lasted between one and two hours and provided an opportunity to develop a therapeutic rapport. The researcher's role as a support aid was explained, before conducting a focused assessment. The assessment explored the participant's current difficulties and the resulting impact of their condition and low mood. The session began with a brief discussion about depression. The content included information on depression prevalence, functional impact, potential symptoms, and changing behaviours in the face of depression. The introduction of behavioural activation, the rationale, and activity monitoring.
Psychoeducation (week 4)	Identifying participants values.	Internet video software	Life areas, values, and activities form Activity ranking/selection form	The session focused on exploring the participant's important life areas, to begin considering and highlighting their values. The participant was introduced to the homework form and given an opportunity to ask any questions.

Session/week	Content	Delivery method	Homework	Overview
Intervention: session 1 (week 5)	Daily monitoring form review. Activity selection. Life Areas, Values, and Activities Inventory: Concept Review.	Internet video software	Complete daily monitoring form Complete activities	This session reviewed the daily monitoring form. Attention was given to activities which the participant was doing and whether the activities are enjoyable, important, gave a sense of achievement or neither. By then introducing the activity ranking and selection task, the participant was supported with planning activities that they believed were not too difficult to engage in, between the sessions. This included increasing the identified enjoyable activities the participant highlighted in their homework.
Intervention: optional session (week 6)	Daily monitoring form review. Troubleshooting.	Internet video software	Complete daily monitoring form Complete activities	This optional session was used for problem solving. Reasons for introducing the session included difficulties in engaging activities, problems with the homework task, and why individuals can find behaviour change difficult.
Intervention: session 2 (week 7)	Daily monitoring form review. Activity planning. Life Areas, Values, and Activities Inventory: Concept Review.	Internet video software	Complete daily monitoring form Complete activities	This session reviewed the daily monitoring form and the planned activities. The review focused on enjoyment, importance, and achievement of activities. The session addressed any difficulties the participant had completing certain activities and how this can be overcome. The session explored activities in relation to the participant's values and that they seem consistent with those values.

Session/week	Content	Delivery method	Homework	Overview
Intervention: session 3 (week 9)	Daily monitoring form review. Activity planning Life Areas, Values, and Activities Inventory: Concept Review.	Internet video software	Complete daily monitoring form Complete activities	This session reviewed the daily monitoring form and the planned activities. The session addressed any difficulties the participant had completing certain activities and how this can be overcome. The session explored the activities in relation to the participant's values and that they seem consistent with those values.
Treatment evaluation (Week 11)	Daily monitoring form review. Preparing for the end of treatment.	Internet video software	None	This session reviewed the daily monitoring form and the planned activities. The session then focused on reviewing the work completed during the intervention and how the participant can continue to apply the skills they had learned.

2.8 Analysis

Online data (from Qualtrics.com) was transferred by LLO to Microsoft Excel, which was used to develop all charts for analysis.

2.8.1 Demographic and feasibility data

Descriptive statistics were used to present participant demographics, including age, gender, relationship status, care support and type (paid /unpaid carers, hours per week), ethnicity, education level, and employment status. Descriptive statistics were used to present information on disease duration and progression.

Data on session length, and feasibility data were analysed using descriptive statistics. Feasibility data described includes recruitment, session attendance, attrition, questionnaire adherence, follow-up, additional support, interviews and acceptability.

2.8.2 MSCED

Visual analysis is the established and recommended approach to analyse single-case experimental design data (Morgan & Morgan, 2008). The analysis identifies any phase-related changes in process and outcome variables. The analysis provided a visual representation of the covariation between process and outcome measures, to explore whether/how the intervention had a positive impact on mood and activation. By using visual analysis in time-series data, responses to measures can be used to assess the dependent variable, as it varies over time in response to the independent variable (Barlow et al., 2008). The collected time-series data were examined using conservative dual-criterion (Fisher et al., 2003). In addition, to calculate treatment effects, the percentage exceeding the median was used (Ma, 2006).

2.8.2.1 Conservative dual-criterion and percentage exceeding the median

Calculating effect sizes has become an increasingly common practice to supplement visual analysis in order to support clinical decisions about treatment effects (Morley, 2018), however no consensus exists on which method should be used with each having relative strengths and weaknesses (Lenz, 2013). The conservative dual-criterion was developed by Fisher et al. (2003) in order to improve on analysis methods such as the split-middle technique and the percentage of nonoverlapping data (Swoboda et al., 2010) to increase inter-rater reliability. A strength of the analysis is that both baseline data and projected trend are used and is reported to have low rates of Type I and Type II errors, which makes the analysis rigorous for single-case experimental design analysis.

To apply the conservative dual-criterion a line for level and a line for trend is drawn on the treatment graph using baseline data. The method aims to control the rate of Type I errors, the level and trend line are set 0.25 standard deviations in the direction of the predicted treatment effect. The method has four steps (Swoboda et al., 2010):

1. Sum the number of data points in the treatment phase.
2. Use the total to identify the number of points in predicted direction needed to conclude that there is systematic change (Table 10).
3. Sum the number of points in the treatment phase that are above both lines where treatment aims for increase, or the number below both lines if treatment aims to reduce.
4. If the number of data points from Step 3 is equal to or greater than the number required by Step 2, conclude that systematic change occurred from baseline to treatment. If not, conclude that there is not sufficient evidence of systematic change.

Table 10

Criteria for concluding that the treatment-phase change is systematic

Number of points in treatment phase	Number of points in predicted direction needed to conclude that there is systematic change
5	5
6	6
7	6
8	7
9	8
10	8
11	9
12	9
13	10
14	11
15	12

Adapted from "Visual Aids and Structured Criteria for Improving Visual Inspection and Interpretation of Single-Case Designs" by Fisher et al. (2003).

In addition to conservative dual-criterion, treatment effect size were calculated using the percentage exceeding the median (Ma, 2006). The percentage exceeding the median is based on the assumption that if there was no effect then treatment phase data points will fluctuate 50/50 below and above the median of the baseline phase. The percentage exceeding the median is calculated by stretching the median from baseline across the treatment phase and counting the number of points that fall above or below the line (if decrease denotes positive change). The number of points exceeding are then compared to the total number of possible to gain a percentage. The percentage is then changed into a score ranging from 0 to 1, by moving the decimal place two places to the left. Scores ≥ .9 indicate 'highly effective treatment', scores between .7 and .9 indicate 'moderately effective', and scores < .7 indicate 'questionable or not effective' treatment (Ma, 2006).

A strength of using percentage exceeding the median is that the approach is less vulnerable to Type II errors as it uses all baseline data which accounts for potential outliers in data sets which may negatively influence the evaluation of an intervention (Lenz, 2013). However, percentage exceeding the median has been criticised for producing inflated effect sizes and Type 1 errors by not detecting changes, or lack of, across phases (Wolery et al., 2010), hence the pairing with conservative dual-criterion.

2.8.2.2 Establishing a baseline

To present depression data for each participant, scores for the PHQ2 collected during baseline were converted to HADS equivalent to track change using a trendline. By calculating the trendline of the PHQ2 during baseline we calculated the value at the intercept at 0 (one observation before baseline: i.e., the pre-intervention datapoint). We then changed the value at intercept to the pre-baseline HADS score and used the trendline to approximate values of HADS depression during baseline. Then, to approximate the intervals used during the intervention phase, we transposed the pre-intervention plus baseline points into three datapoints coinciding with (a) Pre-intervention, (b) Baseline 3, and (c) Baseline 6; this which allowed us to treat datapoints as equidistant and on the same scale (an example of this process can be seen in results 3.4.1).

2.8.3 Clinically significant and reliable change

Visual analysis is supplemented with use of reliable and clinically significant change indices, to provide quantitative decision criteria for identifying the statistical robustness and practical importance of any visually-apparent shifts over time. Jacobson and Truax (1991) developed the clinical significance and reliable change index to assess whether the observed change on pre-to-post questionnaires is large enough to be deemed clinically meaningful and reliable. By referring to

the manipulation of the independent variable and clinically significant and reliable change, an interpretive context for understanding changes is provided (Jacobson & Truax, 1991); this is important when considering the development of larger feasibility studies. Using clinically significant and reliable change allowed investigation across individual participants and an evaluation of each of the single-case data.

Following an intervention, it is important to assess whether an individual experienced meaningful change as a result of that intervention (Jacobson & Truax, 1991). We need to know whether the individual experienced reliable change and, if so, whether the change was clinically significant. The reliable change index is used to determine if change in an individual's pre- and post-intervention score is statistically significant (Jacobson & Truax, 1991). Reliable change indices estimate if change is greater than measurement unreliability and therefore a result of intervention. Reliable change is calculated using the standard deviation and the reliability of a measure. If the change was reliable, we can then assess whether it is clinically significant, which is demonstrated when an individual's score moves from a 'clinical' to a 'non-clinical' range.

Reliable change is calculated by dividing the change in an individual's pre-intervention to post-intervention score by the standard error of change. Standard error of change is calculated using the following formula, where SD is standard deviation, sqrt is square root, and rel is reliability:

SD1*sqrt(2)*sqrt(1-rel)

The calculation indicates the amount by which an individual's score must change to reliably state that change is not due to chance.

Clinically significant change is assessed and achieved in the following three different ways (Jacobson & Truax, 1991).

- Criterion a: an individual's post-intervention score is more than two standard deviations from the mean score of a clinical group.

- Criterion b: an individual's post-intervention score is within two standard deviations of the mean score of a non-clinical group.

- Criterion c: an individual's post-intervention score is closer to the mean of the non-clinical group than the mean of the clinical group.

Reference data used for reliable change indices and clinically significant analyses can be seen in Tables 11 and 12.

HADS. Reliable change indices were calculated using the depression score for all participants with MS (*n* = 4379) mean score (7.6, SD = 4.2, SE = .06) and using the reliability score of 0.82 for the depression subscale (Bjelland et al., 2002). The standard error of change given these values is 2.52. The reliable change criterion is 1.96 times this, i.e., 4.94.

BADS-SF. Reliable change indices were calculated using norms from student (*n* = 28) participants who completed the BADS-SF and using the reliability score of .82. At first assessment the mean score was 25.68 (SD 8.21; Manos et al., 2011). The standard error of change given these values is 4.93. The reliable change criterion is 1.96 times this, i.e., 9.65.

ELS. Reliable change indices were calculated using data from a sample of 439 participants and using the reliability score of .90. The mean

score was 60.80 (SD 7.83; Trompetter et al., 2013). The standard error of change given these values is 3.50. The reliable change criterion is 1.96 times this, i.e., 6.86.

MFIS-SF. Reliable change indices were initially explored from Smith et al. (2018) who used data from two studies of MS participants (*n* = 168) and the reliability score of .761. The mean score was 9.78 (SD 5.11; Smith et al., 2018). The standard error of change given these values is 3.54. The reliable change criterion is 1.96 times this, i.e., 6.93. As two standard deviations from the mean would have resulted in a negative score the mean from the sample was used. The mean score was 14.88 (SD 4.45). The standard error of change given these values is 3.08. The reliable change criterion is 1.96 times this, i.e., 5.98.

SF-12v2. In normative data the mean is 50, scores >50 indicate better physical or mental health than the mean. Scores <50 indicate worse physical or mental health than the mean. Reliable change indices were calculated using data from a study of change in health-related quality of life in a MS population (*n*=3516; Janzen et al., 2013) and the reliability score of 0.80. The physical health subscale mean was 39.88 (SE .17) and mental health subscale mean was 51.78 (SE .16). Standard deviation was obtained by multiplying by the square root of the sample size (59.30). The physical subscale standard deviation is 10.08. The standard error of change given these values is 6.38. The reliable change criterion is 1.96 times this, i.e., 12.50. The mental health subscale standard deviation is 9.49. The standard error of change given these values is 6.00. The reliable change criterion is 1.96 times this, i.e., 11.76.

Table 11

Reference data used for reliable change indices and clinically significant analyses

Measure	Reference study	Sample type	Reliability of measure (Cronbach's alpha)	Clinically significant change criterion
HADS	Jones et al. (2012)	Clinical (All MS types) depression score	.82	Established cut-off
BADS SF	Manos et al. (2011)	Non-clinical	.82	b
ELS	Trompetter et al. (2013)	Non-clinical	.90	b
MFIS-SF	Study sample	Clinical MS	.761	a
SF12v2 PH SF12v2 MH	Janzen et al. (2013)	Clinical MS	.80	a

Note. This table demonstrates the reference data and clinically significant change criterion for the study as outlined by Jacobson and Truax (1991).

[a] HADS, Hospital Anxiety and Depression Scale; BADS-SF, Behavioural Activation Scale-Short Form; ELS, Engaged Living Scale; MFIS-SF, Modified Fatigue Impact Scale-Short Form; SF12v2 PH, Short Form-12v2 Physical Health; Short Form-12v2 Mental Health

Table 12

Reliable change indices values and clinically significant change cut-off scores

Measure	Critical RCI value	CSC cut off
HADS depression subscale	4.94	8
BADS SF	9.65	9.26
ELS	6.86	45.14
MFIS-SF	5.98	2.82
SF12v2 PH	12.50	60.04
SF12v2 MH	11.76	65.54

Note. This table demonstrates the calculated values for reliable change indices (RCI) and clinically significant change (CSC) cut offs.

[a] HADS, Hospital Anxiety and Depression Scale; BADS-SF, Behavioural Activation Scale-Short Form; ELS, Engaged Living Scale; MFIS-SF, Modified Fatigue Impact Scale-Short Form; SF12v2 PH, Short Form-12v2 Physical Health; Short Form-12v2 Mental Health

2.8.4 Interviews

To meet the aim of understanding the participants' experience of the intervention, a method with explicit focus on experience is necessary. Interpretative Phenomenological Analysis (Smith et al., 2009) aims to understand people's experience of a phenomenon and how they make sense and ascribe meaning to the experience. However, this process is driven by data of rich narratives (Smith et al., 2009). The mixed-design of this study better aligned to a framework analysis (Gale et al., 2013). A framework analysis emphasises how both a priori issue, and emergent data driven themes guide development of an analytic framework (Parkinson et al., 2016). This study had predefined areas we wished to explore, and framework analysis explores participant experience, whilst remaining open to discovering the unexpected (Parkinson et al., 2016). Framework analysis has been used to analyse semi-structured interviews in health research (Gale et al., 2013) which is comparable to the present study. Themes used to generate codes

were developed from the research question. Codes were applied to participant's responses and were analysed for patterns. Codes were arranged into a matrix to correlate themes to participant codes.

2.8.5 Intervention fidelity

Intervention sessions were audio recorded and evaluated by an independent researcher. Fidelity was investigated using a set framework, to investigate alliance, and content delivery adherence. In total, 19% of audio recordings were audited to ensure accuracy.

3. Extended results

3.1 Demographics

Demographic information for the participants who did not establish a baseline in the study can be seen in Table 13.

Table 13

Demographic information for participants who did not establish a baseline

Demographic	PS07	PS08
Age	42	63
Gender	Female	Male
Relationship	Married	Married
Care	Paid (14hrs) Unpaid (10 hrs)	Unpaid (35 hrs)
Education	University	School
Employment	Unemployed	Retired
Diagnosis duration	10 years	10 years
SPMS duration	4 years	5 years

Note. Both participants were of white British ethnicity.

3.2 Feasibility

Feasibility data can be seen in Table 14.

Table 14

Feasibility data

Feasibility information	Data
Recruitment	Number of people responded from MS Society advert:7 Number of people given information by the multiple sclerosis team: 4 Number of people identified via word of mouth: 3 Other identification: 3 Total number of people study discussed with: 17 Number of people screened using Hospital Anxiety and Depression Scale: 11 Number of people meeting cut-off and consenting: 8

Feasibility information	Data
	Number of people not meeting cut-off on Hospital Anxiety and Depression Scale depression sub-scale: 3
Session attendance	Data on overall percentage of sessions attended: 100% of scheduled sessions were attended
Attrition	Number of participants dropping out: 1
Questionnaire adherence	Number of questionnaires not completed: 5 during baseline (7.8%) 0 pre/mid/end (0%) 4 weekly (7.3%)
Additional support	2 following screening 1 post-baseline 2 post-intervention
Interviews	5

Note. This table demonstrates the data and information pertaining to feasibility questions in the study.

Of the six individuals who were identified and not screened, one declined, two did not respond after being sent the information pack, two did not have secondary progressive MS, and one did not have a computer.

Of the weekly questionnaires, participant 1 did not complete two and participants 2 and 3 did not complete one. Of the baseline questionnaires, participant 8 did not complete one, participant 4 did not complete one, and participant 5 did not complete three.

3.3 Attrition

One participant withdrew from the study after the second session. The participant completed the change interview.

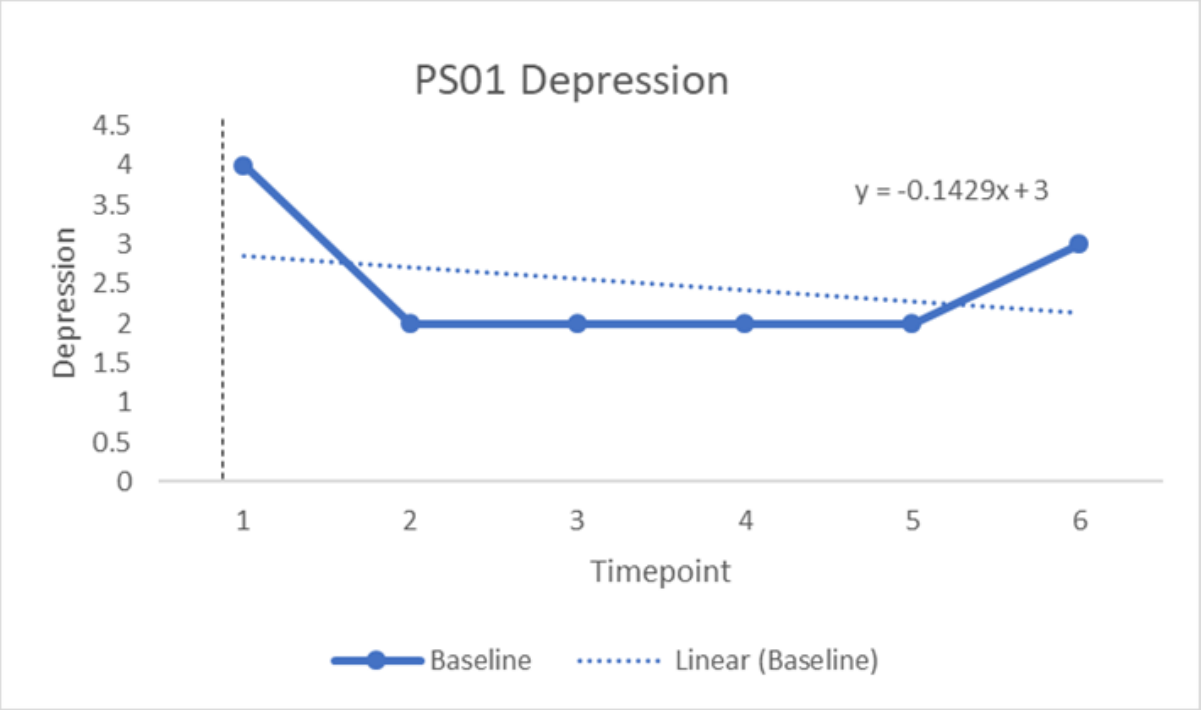
3.4 Baseline data

3.4.1 Example conversion of baseline PHQ2 data to HADS equivalent

The data presented in Figure 8 shows the baseline data for participant 1. Over 6 datapoints participant 1 scored: 4, 2, 2, 2, 2, 3. The resulting trendline equation was y = -0.1429x + 3.

Figure 8

Baseline data for participant 1



Note. Lower scores indicate reduced depression.

By using the value of the intercept at 0 (i.e., 3) and changing the value to participant 1's HADS depression score pre-intervention (14) it was possible to use the trendline to approximate the values of HADS depression during baseline:

Pre-intervention (T0) Depression score (y) = (-0.1429*0) + 14 = 14

Baseline 1 (T1) Depression score (y) = (-0.1429*1) + 14 = 13.9

Baseline 2 (T2) Depression score (y) = (-0.1429*2) + 14 = 13.7

…

Baseline 6 (T6) Depression score (y) = (-0.1429*6) + 14 = 13.1

Then, to approximate the intervals used during the intervention phase, the pre-intervention score was used, and the baseline was transposed in to three datapoints: (1) Pre-intervention (HADS 14), (2) Baseline 3 (HADS 13.6), and (3) Baseline 6 (HADS 13.1).

3.4.2 Baseline trends

In total, two participants (PS07 and PS08) trended to notable improvement during the baseline phase. The responses on the every-other-day measures indicated that they had not been experiencing difficulties with low mood or little interest or pleasure in doing activities. The baseline periods were extended from two to three weeks for participant 4 and the baseline periods were extended from two to four weeks for participants 3, 7, and 8.

3.5 Sessions

Session one lasted between 90 and 120 minutes. Sessions two to six lasted between 38 and 60 minutes. Participants 1,2,3, and 5 requested the additional problem-solving session. Participant 6 did not request the problem-solving session. No sessions were cancelled or missed during the intervention.

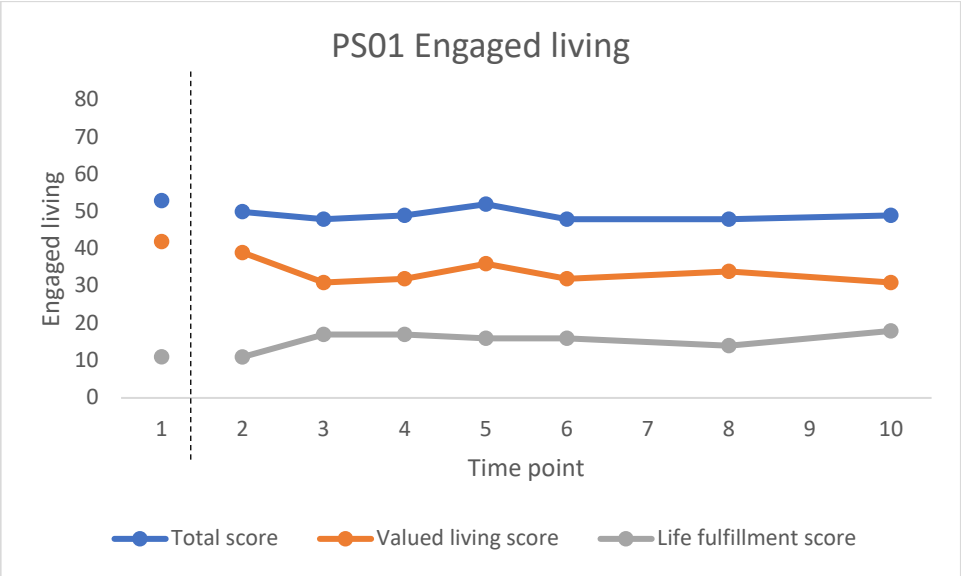
3.6 Process measure - values

3.6.1 Participant 1

Participant 1's ELS scores can be seen in Figure 9. Participant 1's total ELS score at pre-intervention was 53 and post-intervention was 49. Participant 1 started within the non-clinical range and at the study end was still non-clinical. Participant 1 did not achieve reliable or clinically significant change. Participant 1's valued living score pre-intervention was 42 and post-intervention was 31 and represented a deterioration in valued living. Participant 1's life fulfilment score pre-intervention was 11 and post-intervention was 18 and represented an increase in life fulfilment.

Figure 9

Engaged living score for participant 1



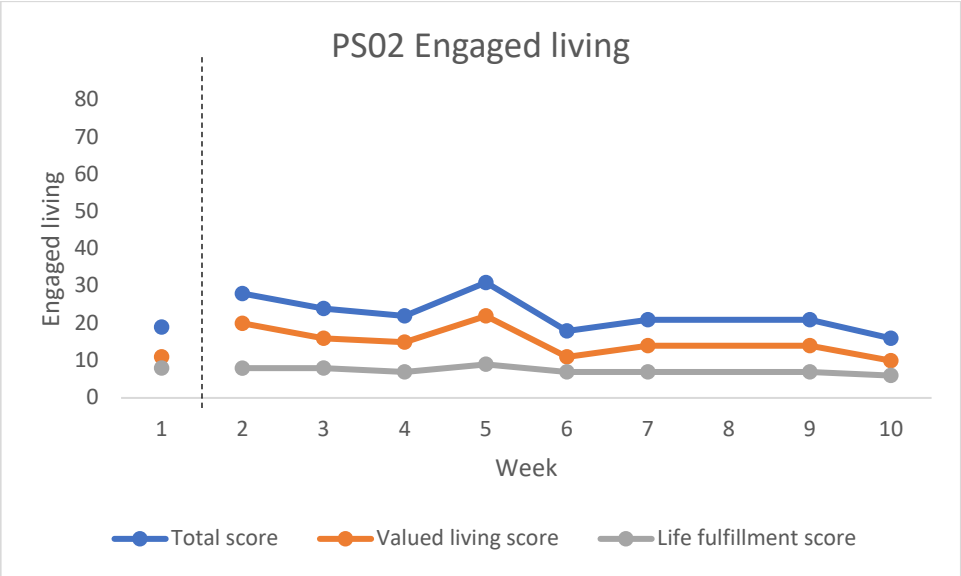
Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.2 Participant 2

Participant 2's ELS scores can be seen in Figure 10. Participant 2's total ELS score at pre-intervention was 19 and post-intervention was 16. Participant 2 did not achieve reliable or clinically significant change. Participant 2's valued living score pre-intervention was 11 and post-intervention was 10 and represented a deterioration in valued living. Participant 2's life fulfilment score pre-intervention was 8 and post-intervention was 6 and represented a deterioration in life fulfilment.

Figure 10

Engaged living score for participant 2



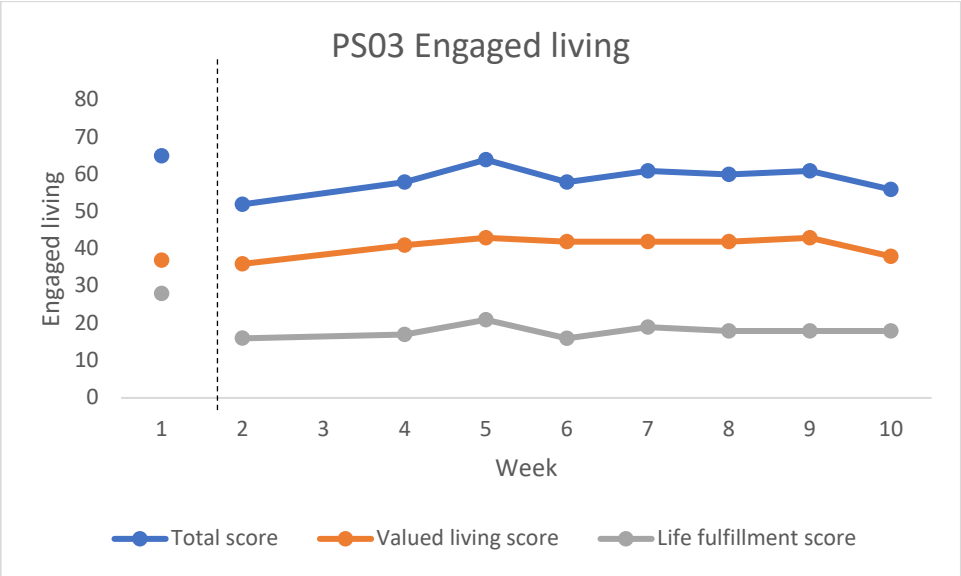
Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.3 Participant 3

Participant 3's ELS scores can be seen in Figure 11. Participant 3's total ELS score at pre-intervention was 65 and post-intervention was 56. Participant 3 started within the non-clinical range and at the study end was still non-clinical. Participant 3 had reliable deterioration. Participant 3's valued living score pre-intervention was 37 and post-intervention was 38. Participant 3's life fulfilment score pre-intervention was 28 and post-intervention was 18 and represented a deterioration in life fulfilment which was more notable than any change in valued living.

Figure 11

Engaged living score for participant 3



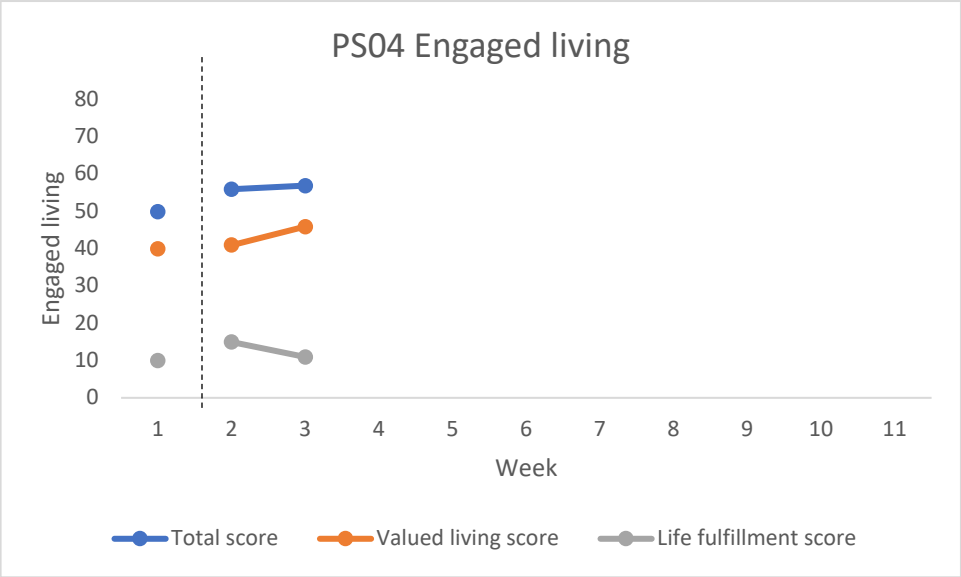
Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.4 Participant 4

Participant 4's ELS scores can be seen in Figure 12. Participant 4's total ELS score at pre-intervention was 50 and at the time of withdrawal was 57. There was reliable improvement but participant 4 started within the non-clinical range. Participant 4's valued living score pre-intervention was 40 and post-intervention was 46 and represented an improvement in valued living. Participant 4's life fulfilment score pre-intervention was 10 and post-intervention was 11.

Figure 12

Engaged living score for participant 4



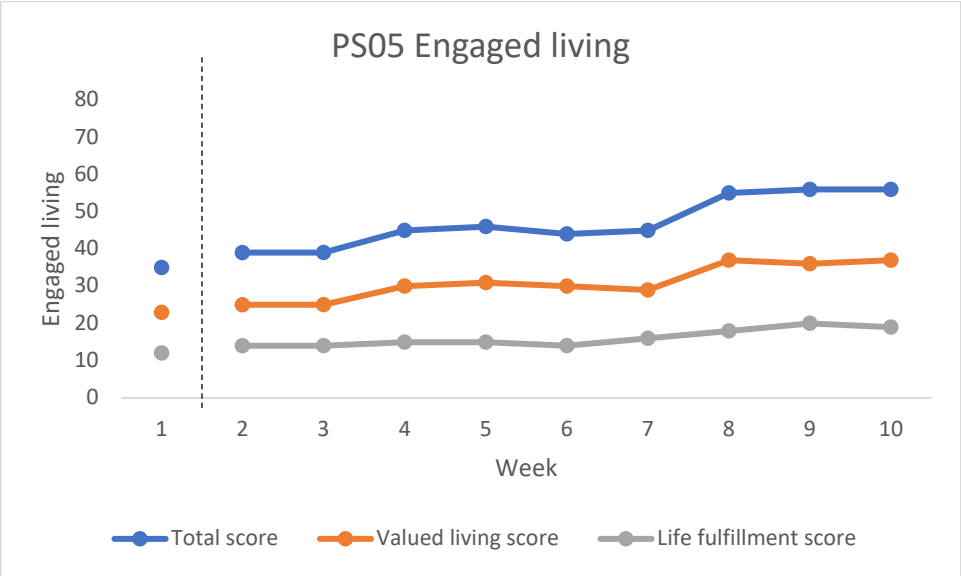
Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.5 Participant 5

Participant 5's ELS scores can be seen in Figure 13. Participant 5's total ELS score at pre-intervention was 35 and post-intervention was 56. Participant 5 achieved reliable and clinically significant change. Participant 5's valued living score pre-intervention was 23 and post-intervention was 37 and represented an improvement in valued living. Participant 5's life fulfilment score pre-intervention was 12 and post-intervention was 19 and represented an improvement in life fulfilment.

Figure 13

Engaged living score for participant 5



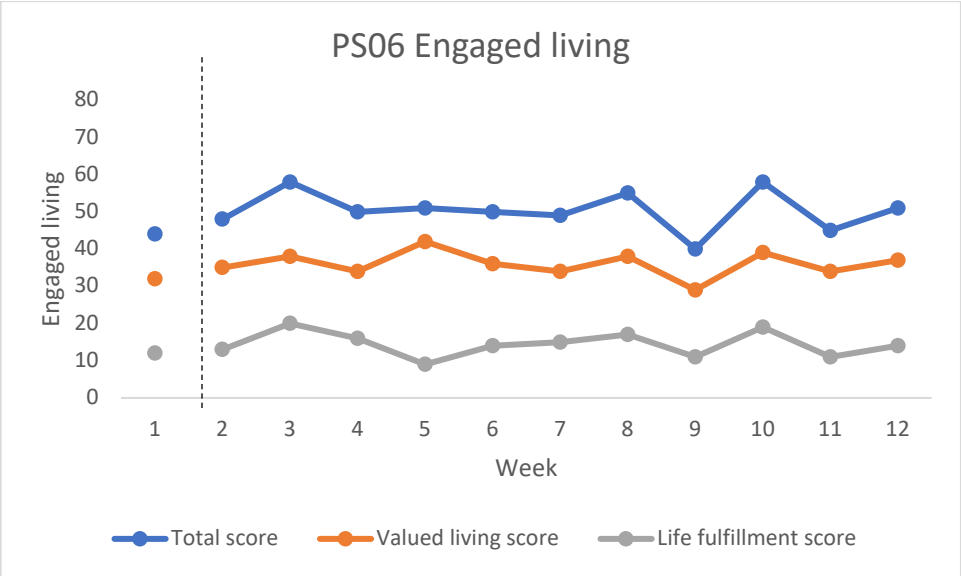
Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.6 Participant 6

Participant 6's ELS scores can be seen in Figure 14. Participant 6's total ELS score at pre-intervention was 44 and post-intervention was 51. Participant 6 achieved reliable and clinically significant change. Participant 6's valued living score pre-intervention was 32 and post-intervention was 37 and represented an improvement in valued living. Participant 6's life fulfilment score pre-intervention was 12 and post-intervention was 14 and represented an improvement in life fulfilment.

Figure 14

Engaged living score for participant 6



Note. This figure shows participant scores for the Engaged Living Scale, including total score and subscales valued living and life fulfilment. Higher scores indicate closer alignment to values, valued living, and life fulfilment.

3.6.7 Synthesis

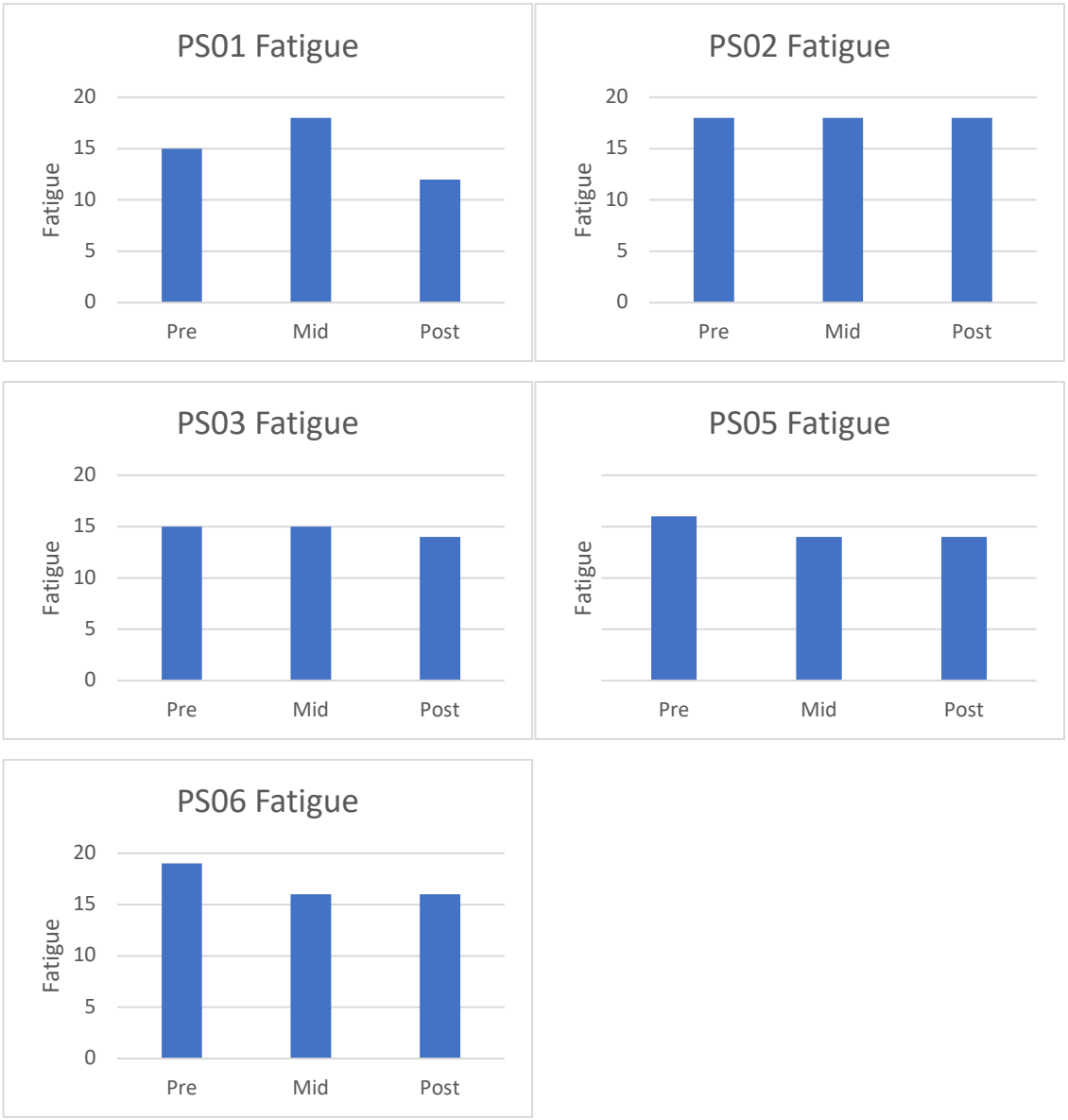
Overall, changes over time were observed in three participants, with two showing reliable and clinically significant improvement and one showing reliable deterioration. Two participants started in the non-clinical range, including the participant who demonstrated reliable deterioration and at study end four participants were in the non-clinical range, including the participant with reliable deterioration. Within the subscales three participants demonstrated an improvement in valued living and three participants demonstrated an improvement in life fulfilment. Conversely, two participants demonstrated a reduction in valued living and two participants demonstrated a reduction in life fulfilment.

3.7 Secondary outcome - fatigue

With the exception of participant 4 (pre-intervention score = 5), fatigue scores ranged from 15 to 19 pre-intervention and 12 to 18 post-intervention in all other participants. The largest change in score was a reduction of three (PS01 & PS06), with no participants having an increasing score in fatigue. Of those where activation increased, no consistent changes were observed in relation to fatigue. Pre-, mid- and post-intervention comparisons for participants can be seen in figure 15.

Figure 15

Participant fatigue scores pre-, mid-, and post-intervention



Note. This figure demonstrates participants' fatigue scores pre-, mid- and post-intervention. Higher scores indicate greater presence of reported fatigue.

3.8 Change interviews

Framework analysis was conducted on the change interviews which were outlined in the journal paper.

3.8.1 Synthesis

Reports varied between those who experienced change and those that did not. In cases of those who did not experience change or withdrew, participants reported not having high expectations of the intervention and that they could not anticipate changing their lifestyle. Comparatively, those that experienced change found the intervention interesting and very good. They reflected on the benefits of being able to use diaries to review their weeks and focus on their mood and how changes came about. They said it was good to be able to take an active role in therapy and still have someone to talk too, rather than just offloading. On occasions the participants found the structure of the diaries (i.e., frequency of recording) laborious, yet, in spite of the time taken to complete diaries participants commented on their usefulness. Even the participants who did not experience change indicated a heightened awareness of their difficulties and having some ideas for solutions, but their perception was that the solutions would have been too hard to put in place.

Participants who experienced change commented on the rapport developed with the researcher which was seen as positive. Participants said that they felt more positive post-intervention than before the sessions and that they were placing things in perspective by reviewing their diaries, which they found helpful as it allowed more emotional capacity to make changes. One participant even highlighted that engaging in therapy had been a platform to improve communication between the participant and their spouse, which had led to additional support from the spouse to help the participant introduce behavioural change by identifying antecedents. In one participant where change was not identified, they commented that they did not think that they were depressed and that they were only experiencing low mood on occasion.

Changes attributed to therapy were linked to diary usage and having space to talk, although initially opening up was hard. Few external attributions were described beyond one participant who reported improved communication which they credited the therapy process to. Lack of changes external to therapy were attributed to identifying mood related difficulties and some potential solutions but they did not know how to implement them and that they did not anticipate any change due to being 'set in their ways.' External factors associated to non-change and barriers to change were the participant's MS symptoms. They reported being able to highlight difficulties associated to low mood and think about some solutions but commented that the amount of additional time it takes to complete activities (e.g., activities of daily living) meant that they had less time to implement new activities. A number of stressors were reported across all participants including MS symptoms, reliance on others, not having time, and ill health amongst loved ones.

The flexibility of the researcher and sessions, and the questionnaires being online were reported as helpful. Overall, the intervention appeared to increase self-reflection, problem solving, and an increased awareness of shared experiences, with the biggest barrier to change being ill-health.

3.9 Fidelity

From the BATD-R checklist, the following competencies were assessed, Session one: (a) Confidentiality; (b) Discussion of depression; (c) Treatment rationale; (d) Daily monitoring form (importance, enjoyment, and achievement ratings, and when should you complete the form; (e) Important things about the structure of the treatment. Session two: (a) Daily monitoring, review homework and troubleshoot; (b) Treatment rationale review; (c) Values identification and forms. Session three: (a) Daily monitoring, review homework and

troubleshoot; (b) Values identification and forms review; (c) Activity selection and ranking; (d) Daily monitoring with activity planning. Session four: (a) Daily monitoring, review homework and troubleshoot; (b) Daily monitoring with activity planning. Session five: (a) Daily monitoring, review homework and troubleshoot; (b) Values identification and forms review; (c) Daily monitoring with activity planning. Evaluation session: (a) Daily monitoring, review; and (b) planning for the future.

Recordings were selected such that each of the five sessions in the intervention plan and evaluation session were represented at least once, and no two sessions were from the same participant (i.e., maximising variation across sessions and participants). Sampled sessions were: PS01S1, PS02S3, PS03S4, PS04S2, PS05Evaluation, and PS06S5.

3.10 Participant summaries

Participant 1 attended all sessions and took part in the change interview. No reliable change was found in depression, activation, engaged living, fatigue, or health related quality of life. Visual analysis showed a slight trend to improvement in depression, though participant 1 did not move to clinically significant improvement or demonstrate systematic change using dual-criterion. Visual analysis showed no trend to improvement or deterioration in any other outcome. Effect size for percentage exceeding the median was highly effective for depression on the HADS depression subscale and moderately effective on activation on the BADS-SF. Participant 1 reported in sessions that they could not try many new activities due to their MS. Additionally, they reported that the amount of additional time that it takes to complete daily activities makes it hard to find time to implement solutions to difficulties that had been identified during sessions. Homework adherence was poor with in session reporting

noting that diaries or activities were not planned. At treatment end Participant 1 did not want an onward referral.

Participant 2 attended all sessions. No reliable change was found in depression, activation, engaged living, fatigue, or health related quality of life. Visual analysis showed no trend to improvement or deterioration in any outcome, although on conservative dual-criterion they were one observation off showing systematic change on the HADS depression subscale. Effect size for percentage exceeding the median was moderately effective for depression on the HADS depression subscale and questionable or non-effective on activation on the BADS-SF. Participant 2 reported a relapse in symptoms which coincided with a levelling off in measures. Participant 2 was particularly worried about the effect of their symptoms on their speech and requested not to take part in the change interview. Participant 2 regularly completed homework and self-opted to email their diaries ready for sessions. Participant 2 reported an increase in activity and enjoyment, achievement, and importance in the activities but when completing the outcome measures, he reported not engaging in activity and little improvement in mood. Of note, participant 2 found discussing values very difficult and that the time spent on highlighting their values instead highlighted a lack of values and valued living which participant 2 found distressing. Participant 2 requested an onward referral to therapy after taking part in the study commenting that there were a number of difficulties they wanted to explore in therapy.

Participant 3 attended all sessions. No reliable or clinically significant change was found in depression, activation, fatigue, or health related quality of life. Reliable deterioration was found in engaged living, but the participant started and remained within the non-clinical range pre- and post-intervention. Participant 3 was at clinical cut off for non-clinical depression at the end of intervention. Effect size for percentage

exceeding the median was highly effective for depression on the HADS depression subscale and activation on the BADS-SF. Participant 3 reported being unwell and spent a brief period in hospital during the first few weeks. They indicated that the illness and made them feel increasingly fatigued. Additionally, participant 3's mother was very unwell throughout the intervention, during the sessions participant 3 became tearful on a number of occasions when discussing this. Further, participant 3 reported a number of friends had died during the intervention which had been particularly upsetting. Despite the external stressors, visual analysis showed a trend to improvement in depression and activation. Participant 3 regularly completed homework tasks and completed the change interview. Participant 3 reported that having the space to talk and to be able to reflect on behaviours using their diaries was helpful. Participant 3 declined an onward referral.

Participant 4 attended two sessions and then withdrew. Participant 4 agreed to take part in the change interview. Participant 4 stated that it was not worth trying new activities because nothing would change and that any planned activities, he could predict what score he would rate enjoyment, importance, and achievement before doing them. Participant 4 said that no number of questionnaires would change his mood because his MS is a condition, that he has all the time.

Participant 5 attended all sessions. Improved reliable and clinically significant change was found in depression and engaged living. Reliable change was seen in activation and mental health related quality of life to improvement. Visual analysis showed an improvement in activation from baseline. Systematic improvement was not seen in depression scores but were one observation away from meeting criteria. Effect size for percentage exceeding the median was moderately effective for depression on the HADS depression subscale and highly effective on activation on the BADS-SF. Participant 5 took part in the change

interview, completed homework and at evaluation reported feeling better and did not wish to be given any additional information for on-going psychological support. Participant 5 reported finding the process of scheduling activities very helpful and attributed positive changes to mood.

Participant 6 attended all sessions, the length of the time in the study was longer than other participants because the participant did not wish to have a session during the Christmas and New Year holidays. Participant 6 completed outcome measures during those two weeks. Reliable and clinically significant change was found in depression and engaged living. Reliable improvement was found on the mental health related quality of life. Visual analysis showed a trend to improvement in depression. Effect size for percentage exceeding the median was highly effective for depression on the HADS depression subscale and moderately effective on activation on the BADS-SF. Participant 6 completed homework and took part in the change interview. At evaluation they reported feeling better in mood and declined an onward referral. They reported positive improvements in communication with their spouse and receiving support to identify antecedents to low mood to change behaviour. The participant used the diaries to identify patterns of behaviour that maintained low mood and used the diaries day-to-day to help support changes when they were feeling low. The participant also began to evaluate behaviour by asking themselves what they would say to a friend who was experiencing similar distress or changes in behaviour.

Participant 7 showed a trend to improvement during the baseline phase. When discussing changes at debrief they indicated that they were feeling much better in mood and declined any information for seeking psychological support.

Participant 8 showed a trend to improvement during the baseline phase. When discussing changes at debrief they indicated that they thought that the increase was likely the result of it being Christmas. They believed it would be a temporary improvement and they requested information to self-refer to psychological therapy.

4. Extended discussion

We aimed to (a) examine preliminary efficacy of a behavioural activation intervention, for people with secondary progressive MS experiencing low mood, (b) understand the feasibility of recruiting, retaining, and delivering the intervention, (c) explore whether/how the intervention has a positive impact on mood, fatigue, and quality of life using process measures, and (d) understand participants' experience of the intervention.

4.1 Effectiveness

What works clearing house reports that single-case designs aim to assess causal questions such as: "Is this intervention more effective than the current "baseline" or "business-as-usual" condition?" (Kratochwill et al., 2010, pg3). More specifically, does the introduction of an independent variable have a causal relationship with a change on the dependent variable. In the case of this study we wanted to understand whether the introduction of behavioural activation (independent variable) had a change on depression (dependent variable) in individuals with on-going and declining physical health difficulties. Secondly, to understand mediators and moderators we wanted to understand whether behavioural activation increased engagement in positively reinforcing behaviours and a decrease in maintaining behaviours of depression. If so, does increased engagement in positively reinforcing behaviour coincide with the introduction of therapy sessions focusing on behavioural activation which then has a positive effect on depression. Single-case designs are particularly fitting to the pursual of research questions in applied and clinical settings (Kratochwill et al., 2010).

It is important to consider whether effectiveness can be observed in populations where prevalence is considered lower than general

population studies because high powered group studies can be difficult to conduct (Kratochwill et al., 2010). When only group designs are considered it is not possible to understand the minutiae of who responded to an intervention and outcomes can be obscured when only reporting effect sizes and/or group means. Helpfully, the design of the study allows us to consider the characteristics of those participants that did change and those that did not experience change which is important when considering effectiveness and future research or application.

Effectiveness in single-case experimental designs is typically considered as replication. That is, "in most cases experimental control is demonstrated when the design documents three demonstrations of the experimental effect at three different points… or across different cases" (Horner & Spaulding, 2010). Further, experimental effect is demonstrated when there is a covariation with the manipulation of the independent variable and predicted changes in the dependent variable, but there is no formal basis for three demonstrations rather it is just a conceptual norm (Kratochwill et al., 2010). It is also difficult to draw valid causal influence from AB designs due to the lack of replication which means it is harder to rule out alternative explanations for changes that are observed (Kratochwill et al., 2010). However, as therapeutic learning cannot be taken away introducing later phases is not possible. In an attempt to overcome some of the difficulties in exploring causality, baselines were established in this study, which in some cases meant differing lengths of baseline.

During the baseline one participant was observed to be increasing their activation, based on their reporting on the BADS-SF. It is possible that expectancy effects were occurring. Expectancy effect occurs when an individual begins to react unconsciously because they expect a given result. The expectations that are unconsciously responded to occur

naturally and can be introduced by the process of giving individuals specific information prior to therapy and may contribute to therapeutic outcomes (Tambling, 2012). In an attempt to mitigate any expectancy effects that may have occurred from responding to measures asking about activity levels every-other-day, minimal information was given about the process of behavioural activation. Further, the analysis method incorporated the use of baseline trends and stability (conservative dual-criterion). However, participants were aware that the study aimed to reduce low mood by increasing activity levels.

Visual analysis is used to investigate replication effects but each of these differ (discussed earlier), in this study conservative dual-criterion was used along with percentage exceeding the median. Data were supplemented with reliable change indices. When using conservative dual-criterion method, the intervention failed to demonstrate three replications, but when considering percentage exceeding the median analysis the condition is satisfied. When using analyses to triangulate, the criteria are satisfied but the variation in scores across measures made interpretation difficult and as such considering the criteria satisfied should be used with caution. It does however provide a basis to consider group effects.

Where no change was observed in low mood scores nor was any change in activation scores, which when paired with the evidence that increased activation scores led to a reduction in depression, the behavioural theory that increasing environmental positive reinforcement and reducing maintaining behaviours has a positive effect on depression is demonstrated. Whilst in some participants the sessions led to increased engagement in activation, the question remains as to why this was not observed with all participants. Potential theories to explain this observation are discussed in the next sections.

There is an association with poor physical health and decreased mood (Kings Fund, 2012). In secondary progressive MS individuals' symptoms do not remit and continue to worsen. Using the baseline trajectories for some participants may lend some support that a lack of reduction in depression scores may still be a positive outcome. For example, where trajectories were increasing for worsening mood, if we assume that physical health continues to be poor or declining does a levelling off of mood represent a positive change. Certainly, in the case of participant 3 they reported benefits from the intervention to their mood despite having been ill and experiencing external destressing stressors. Whilst the idea that a levelling off of mood scores in the face of external stressors/physical health decrease warrants further exploration, we are still left with the question of why in some cases improved mood observed?

Using repeated measurement strategy and the BADS-SF means we can be somewhat confident that the intervention was effective; at least when activation was increased. However, there were cases where improvements in activation did not occur. For participant 2 there appeared to be a slight change in activation and mood when the activity planning sessions started but following a relapse in MS symptoms activation reduced and mood increased, which is congruent with the theory around positively reinforcing activities and mood. Of particular interest with participant 2 was self-reporting during the intervention. Participant 2 emailed his activity diaries for each session and talked through them, commenting on a number of activities that he was engaging in, enjoying, and deriving a sense of achievement. Despite these reports when completing post-session measures, he repeatedly scored indicating that he was avoidant of activities and was not enjoying. It is possible that demand characteristics led him to comment on enjoying activities, but the session were structured to cover 'what we did not do, did not enjoy, and to think about obstacles.' If the

sessions had only focused on discussing positive activities it is possible there would have been an increased pressure to then find and discuss enjoyable activities, but as time was spent (as highlighted in fidelity assessments) on identifying and focusing on negative behaviours this was less likely the case. During the intervention participant 2 found discussing and identifying values difficult. Participant 2 often discussed childhood experiences and wished to explore childhood further, commenting that he had bought a compassion focused therapy book and identified with many of the examples and could relate to the approach. He discussed being hopeful that post-intervention that I would support him to make a referral to work with a psychologist using compassion focused therapy. It is possible that secondary gains were occurring, and he thought that he needed to score high for distress so that an onward referral would be discussed post-intervention. During the session recordings he discussed a number of things that he found helpful about the approach, including having someone to discuss his distress with, but as his symptoms relapsed, he was particularly worried about his speech and that he was embarrassed that CM (interviewer) would not understand him. He had agreed to take part in the change interview but did not respond to attempts to contact him.

4.1.1 Attrition

Only one participant withdrew during the study. The participant withdrew after the baseline and after session two, which was prior to any activity scheduling activities and only during the activity monitoring period. The point in which the participant withdrew did not occur at a critical time, which if they had, might compromise the study's internal validity and render any causal inferences invalid (Kratochwill et al., 2010). The participant's scores were similar at baseline to those that remained in the study. There were no apparent differences about this participant versus those that completed the

intervention. Baseline had achieved stability and there were no visually apparent differences compared to completers. The participant reported that they did not see how their mood could change because their MS would always be present. It is possible that completing the questionnaires and diary sheets highlighted to the participant the difficulties in planning behaviour. Certainly, they talked about their dependence on others to help enable them and give them access to activities. It is possible that the participant was experiencing learned helplessness (Seligman, 1972; Seligman & Maier, 1967) discussed below.

4.2 Findings in context of previous research and theory

4.2.1 Behavioural theory and behavioural activation

Behaviourism is founded in the use of scientific and objective methods to investigate occurrences (Watson, 1913). By using single-case experimental design we were able to explore behavioural responses to the introduction of intervention in phases.

In the first phase (baseline) we were able to investigate the behavioural responses of depression, as such we were able to observe conditioned behaviours through the participant's interactions with their environment before change was introduced; allowing us to see how people's actions are influenced by environmental stimuli (Stout, 2003). At the start of the second phase (intervention) participants were asked to make a diary of their activities and rate behaviour in order to gather evidence for how their mood was impacted by environmental stimuli. However, a level continuation of low mood was not observed as expected; it had been assumed that change in mood would likely occur at the point of scheduling activities (after several sessions). It is important to note that giving participants questionnaires and diaries to keep is an introduction of a behaviour change. As, participants were

able to think about their activity levels, values, and use their diaries to note when their mood was better or worse which may have led to behaviour change.

Thus, the process of observation in itself may have led to change, which may explain the increasing activation baseline scores for participant 6 for positively reinforcing behaviour. Behavioural theory posits that depression is maintained due to schedules of reinforcement (Skinner, 1953). We know that the prominence of a stimulus affects the strength of association in behaviour, perhaps when participants were observing their mood and behaviour, and answering questionnaires which are designed to make them think about enjoyable activities there were unintended consequences. Specifically, that some behaviours were changed or put on an extinction schedule.

The improvement in mood coinciding with positively reinforcing activities as the intervention went on may be a demonstration extinction schedules in effect. The gradual changes observed may be a demonstration of the association between stimuli weakening and then stopping. Skinner (1948) lends support to the notion of weakening stimuli as he reported that the rate of extinction is affected by the original response, i.e., the longer a behaviour has been conditioned the longer it can take for the behaviour to become extinct. In the participants, delayed extinction was seen as maladaptive coping strategies and avoiding activities.

Despite extinction being observed in some participants other participants did not demonstrate any change in mood or positively reinforcing behaviour. It is important to consider the lack of change in behaviour from a theoretical perspective. In depressed individuals reduced activity is the result of a lack of reinforcement in activities that were previously reinforcing (Ferster, 1973). The loss of reinforcement

may be explained by factors such as relational, occupational, or social activity reduction, thereby removing positive reinforcement for an activity and for behaviours that precede the activity. Certainly, based on the participants that did not change they commented on their dependence on others (paid carers) and the reduced time that they had to try and place in new activities to bring about change because of their MS symptoms. Comparatively, participants 5 and 6 reported receiving increased support from significant others to help with their engagement in activities which were thought to provide access to environmental reinforcement. Therefore, receiving additional support or the perception of how much control one has may influence extinction.

When depression occurs with declining physical abilities, individuals find it difficult to identify and engage in new activities that have pleasurable or reinforcing consequences, which has been demonstrated in people with MS (Motl et al., 2009). Despite the finding by Motl et al. (2009), with guidance, participants were able to identify new activities and in cases also engage in them to have a positive impact on their mood. Identifying and engaging in activities that provide environmental reinforcement is congruent with Lewinsohn's (1974) theory of depression and the results of the study are supportive of the theory. Further, by using techniques such as activity monitoring and scheduling (Jacobson et al., 1996), which aims to address environmental deficits in positive reinforcement, behavioural activation decreased depression.

4.2.2 Behavioural activation and neurological conditions

Over the years a number of meta-analyses have been conducted and demonstrated the efficacy of behavioural activation (Cuijpers et al., 2007; Ekers et al., 2008; Mazzucchelli et al., 2009). Further, in a

systematic review of behavioural activation for depression in individuals with neurological conditions (Oates et al., 2019), eight of the ten studies reported a positive outcome for behavioural activation. Similar adaptations were made in the present study such as the use of telephone-psychotherapy and the effect sizes were comparable to the studies reported in the systematic review. There are still a number of differences worth considering in regard to the populations studied in the systematic review. For example, individuals with secondary progressive MS have declining physical health and cognition. In the systematic review, benefits were reported using behavioural activation for depression in stroke, epilepsy, and brain injury populations, where typically, continued deterioration is not observed. Support for behavioural activation for depression was found with people with dementia, but study adaptations frequently used carers or family members to introduce behaviour change and report perceived mood. In this study, using guided self-help participants were able to observe and engage in activity despite declining physical health and cognition.

4.2.3 Theory of planned behaviour

The theory of planned behaviour (Ajzen, 1991) can provide additional understanding to the results from the current study, for both changes and non-changes. Help seeking behaviour is contingent on three critical factors, they are: attitudes towards help-seeking, intention to seek help, and actual help-seeking behaviour (Gulliver et al., 2012). Involvement in research does not necessarily mean that an individual is planning to make changes to self, instead the primary driver may be to engage in research or to help others. Still, each participant was aware of the study and the intervention and chose to take part. The route in which participants entered the study varied. With some participants being provided information by their MS Clinical Care Team and others receiving information through the MS Society support

branches. It is possible that participants attended their routine clinical appointments and were asked about their mental health which led to an unplanned discussion and being provided with study information. Therefore, the individual may not have had the intention of seeking support for mental health but further understanding of what drew each participant to the study is needed.

As mentioned, each participant was aware of the study and the intervention when they agreed to take part, so if opportunistic conversations of presentations removed intention to seek in help-seeking theory, continued engagement in the study is not explained. Only one participant withdrew, and no sessions were missed, which may suggest that help-seeking attitudes for mental health are considered positive. Understanding subjective needs can further explain engagement because individuals seek support to solve their problems and having an awareness of one's subjective needs influences decisions on whether or not to seek help (Gross & McMullen, 1983).

The theory of planned behaviour (an extension of theory of reasoned action) posits that the best predictor of behaviour is the intention to act. Intention is an individual's attitude toward behaviour, subjective norms, and perceived behavioural control. Therefore, if an individual evaluates a behaviour as positive (attitude), and they believe that other individuals, such as family or professionals, want them to engage in the behaviour (subjective norm) then the individual's motivation is higher, and they are more likely to engage in the behaviour (Ajzen, 1991). Later, an additional factor was added to the likelihood of intention and behaviour which was the perceived ease or difficulty that the individual can carry out the behaviour. In the case of the participants, those without immediate familial support and who were dependent on paid carers either did not demonstrate change or

withdrew. It is possible that without subjective norms belief in behaviour change was less. Or in behavioural theory terms there was a lack of environmental contingent reinforcement from family or friends commenting on change or providing praise.

4.2.4 Learned helplessness

Learned helplessness is a phenomenon that occurs when an individual has been subject to repeated exposure to aversive stimuli that is beyond their control. As such, in cases of depression the individual's real or perceived absence of control of an outcome may account for the maintenance of low mood (Seligman, 1975). For participants 1 and 4 they indicated in their sessions and in the change interviews that they cannot change the activities that they do and have less control due to their dependence on carers, who may not arrive at set times, or because of the additional time activities take to complete. Indeed, early research into helplessness posited that an individual's acceptance of powerlessness resulted in learned helplessness. Therefore, attempts to escape or avoid aversive stimuli cease even when presented with alternatives. Over time, learned helplessness may generalise to other situations (Hiroto & Seligman, 1975), as individuals with secondary progressive MS have no control over their physical symptoms it may be possible that a generalisation occurs to agency for their mental health. More recently, studies have indicated that individuals' default state is one of no control and that helpfulness is the state which is learned (Maier & Seligman, 2016). As such, introducing the idea of helpfulness supports the results of this study where changes were observed and gives optimism that helpfulness can be learned with an appropriate reinforcement schedule, yet more information is needed from the individuals who did not change to better understand where to intervene.

Whilst the initial studies that led to the observation of helplessness were behavioural, the findings on the two-factor theory of avoidance learning led to researchers assuming a cognitive role in learning is required (Maier & Seligman, 2016). For example, according to Peterson and Seligman (1984) how someone interprets an event impacts the likelihood of helplessness and subsequent depression. However, behavioural theories such as relational frame theory have gone some way to provide a behavioural overview of the generalisation of behaviour (Hayes et al., 2001).

The presence of helplessness and/or how someone perceives an event impacts their physical and mental health. For example, someone who perceives events as uncontrollable have worse outcomes on physical and mental health and as such are less likely to change unhealthy patterns of behaviour (Henry, 2005). There appears to be a bidirectional impact on depression and social impact where learned helplessness is present. The impact demonstrates the complex interactions that are occurring for individuals because without the presence of helplessness, depression impacts social activity (Lewinsohn, 1974) and lack of social activity impacts depression (Wilkinson & das Nair, 2013). Therefore, unpicking the interactions to target interventions may be better achieved with a detailed assessment rather than a one size fits all manualised approach for all.

In terms of those with secondary progressive MS long-term presentation of helplessness may be explained by Abramson et al. (1978). Abramson et al. (1978) stated that the inability to escape would only result in momentary helplessness. Instead, the attributional reformulation that individuals make of what causes their helplessness predicted the length and extent of helplessness. When individuals attributed helplessness to unsolvable problems, long-term helplessness was observed. In the case of those with secondary

progressive MS the continued progression of the disease and increasing disability may maintain helplessness.

4.2.5 Self-efficacy

Along with ideas of learned helplessness, processes of attribution may be explained by self-efficacy (Bandura, 1982). Self-efficacy is the concept of how much ability one has to deal with situations, or simply put, one's agency. When we are able to understand the beliefs that an individual has about their power and ability to affect situations, we can influence the power an individual has and how they face challenges, which is particularly important when considering health related behaviours. As reduced self-efficacy is associated with predicted health behaviours (Luszczynska & Schwarzer, 2005).

In research and interventions aimed at behaviour change considering self-efficacy is important because individuals are likely to avoid tasks when self-efficacy is low and engage in tasks when self-efficacy is high (Muris, 2002). Where it may not be possible to put behaviours on an extinction schedule using reinforcement, interventions may be supported by raising self-efficacy in order to increase the likelihood of behaviour change. The sooner the environmental reinforcement occurs the more likely a behaviour change and maintenance is. However, when the avoidance of behaviour does not provide an opportunity for reinforcement, we need to understand how best to ensure that a behaviour occurs or how to prevent avoidance behaviours. As therapists are not present at all times to introduce antecedent control it may be that raising self-efficacy may be a way to support people to engage in behaviour change or overcome reduced motivation.

Reduced motivation is associated with depression (National Institute for Health and Care Excellence, 2015). In behavioural activation

individuals are encouraged to, rather than waiting for motivation to return, engage in activities and motivation will occur after repeated reinforcement (Lejuez et al., 2011). However, if competing reinforcement is perpetuating avoidance behaviours and therefore starving a participant of positive environmental reinforcement then considering an individual's self-efficacy may be of further benefit as those with low self-efficacy are less likely to try or maintain efforts to complete tasks than those with high self-efficacy leading to learned helplessness.

4.2.6 Secondary gains

During the intervention some participants did not report any changes. In particular, one participant reported positive experiences in activities and psychological wellbeing in the sessions but on measures reported the opposite. It is possible that as an individual loses contact with their activities that a verbal preoccupation with the loss can occur (Azrin & Besalel, 1981; Ferster, 1973). Verbal preoccupation can present in a number of ways such as crying or complaining to others. In the case of participant 2 verbal preoccupation presented as repeated discussions about not having any values nor having lived a life as such. The participant used sessions to often talk about childhood and needing guidance to focus back to behavioural activation. As such, it was discussed with the participant that further therapy may be of benefit and the participant was very keen to explore how to get an onward referral post-intervention. It is possible that the incongruence between self-report in sessions and measures was linked to a secondary gain of receiving future therapy if mood continued to present as low. Verbal behaviour may be positively reinforced by individuals around the depressed person as the system offer sympathy, leading to an increase in the unhelpful behaviour (Azrin & Besalel, 1981). Unfortunately, participant 2 did not take part in the change interview, the withdrawal

from the change interview coincided with a MS related symptom relapse where the participant had difficulties speaking. The participant did contact on two occasions post-intervention to discuss onward referral and discuss therapy types with the hope to spend time thinking about childhood and the role of self-criticism.

4.3 Values

This study, in the cases of participants 1 and 2, did not appear to make improvements in people moving toward identifying their values and engaging in valued activity. Instead, both participants reported difficulties identifying values and living a valued life as they compared their current capability to their abilities pre-MS diagnosis. The number of sessions delivered in the study and the pace of the sessions meant that a set amount of time was designated to the establishment of values. The number and length of sessions were selected in order to keep in line with comparable therapy initiatives like IAPT. However, in this study establishing values was difficult and provides an insight into the difficulties of rigid manualised interventions as there is an assumption that all individuals will progress at the same rate.

The use of the measures may have had unintended consequences, in that participants were regularly reminded of their difficulties. In ACT, this process is not problematic as reduction in mood is not the desired outcome but in behavioural activation reducing depression is theoretically aligned to the idea that increasing environmental reinforcement reduces depressive behaviour.

4.4 Fatigue

It was hypothesised that an increase in activity measured by the BADS-SF would demonstrate favourable effects on fatigue. There appears to be cyclical effect of low mood leading to fewer activities and fewer activities leading to low mood. In studies of increased activity or

exercise in people with chronic fatigue, individuals report reduced fatigue and, in some cases, improved psychological wellbeing (Larun et al., 2015). Notably, in this study no changes were observed to fatigue whether activation increased or remained the same. It is possible that in this case participants were selecting positively reinforcing activities that did not include exercise or physical activity as a component. Despite the lack of change to fatigue, outcomes suggest that when individuals are able to support themselves to engage in activities fatigue was not a reported barrier and positively fatigue did not increase and represent a barrier.

4.5 Feasibility

4.5.1 Recruitment

The strategy used in this study for recruitment was feasible. However, for a larger trial would need further consideration. More participants were identified and recruited from MS Society local groups than the MS Clinical Care team. Should the recruitment strategy be expanded increased involvement from multisite NHS trusts would be necessary. Clinic appointments are often fast paced with both clinicians and patients having agendas to cover in the time frame. As patients often only see clinicians in the recruiting service six-monthly, considering approaches such as contacting patients from a database would be beneficial. In some trusts having a database of people interested in research and their condition has been achieved as part of routine care questions asked at review, with patients opting into communication.

It is possible that the participants included in this study may be more motivated to take part and engage in psychological therapy than those who did not. Conducting a feasibility randomised-controlled trial as directed as the next step in the MRC framework would provide further information on recruitment strategy and attrition.

4.5.2 Session delivery

Sessions were delivered via the telephone or using Skype. No sessions were cancelled or missed. However, conducting sessions using technology allowed increased flexibility due to participants not needing to arrange transport or the clinician not needing to arrange therapy rooms. As a result, it was possible to provide increased flexibility to session time, dependent on the diary of the clinician which was evidenced by moving the time of one or two sessions. Being able to move the sessions was beneficial as it allowed people to engage in activities which they had planned as part of their activity goals.

The number of sessions was acceptable to participants, however, significant changes to values was not observed. Participants reported that the concept of values whilst helpful was difficult to grasp. Additional time would be needed to facilitate greater support to identification of values. However, changes were observed despite difficulties to values identification which warrants additional investigation into the necessity of values components which could be facilitated in a three-arm feasibility trial (control, behavioural activation with values component, and behavioural activation without values component).

4.5.3 Materials

Participants reported that the BATD-R manual was understandable, and the worksheets were easy to complete. However, participants reported that the time frequency was too high on the diaries, additional room needed to be added for those with difficulty writing, and half of the participants preferred to complete diaries electronically.

4.6 Strengths and limitations

The study contributes a structured design to investigate mediators and moderators of behavioural activation for depression in individuals with

secondary progressive MS. The study was designed with the aim to balance between ecological validity and experimental control. Multiple single-case experimental design studies require a critical in-depth analysis but often produce a varied picture in terms of effectiveness. Whist the results begin to demonstrate that people with secondary progressive MS can identify and engage in activities to increase positive reinforcement and reduce depressive symptoms, the outcomes among all participants was slightly varied and therefore does not provide clarity on the efficacy of behavioural activation for people with low mood and secondary progressive MS which may have been captured by a design such as a randomised-controlled trial.

This multiple single-case experimental design study is an initial approach to examine the effects of behavioural activation on depression for people with declining physical health (i.e., secondary progressive MS) which used a multimodal, multi-measure approach which was a data-intensive design. The design provided the benefit of triangulation opportunities (Webb et al., 1966) by collecting relevant data that reduced the likelihood of missing important information.

A number of measures were used to provide detailed information in regard to mood, behaviour change, fatigue, values, and quality of life. Additionally, there were a good number of data collection points which is important in visual analysis and case series data. However, the repeat effects of measures can be problematic. As discussed, the measures may have contributed to behaviour change due to increased awareness of one's behaviour which threatens internal validity. Further, the use of repeated measures could lead to iatrogenic effects. For example, participant 2 discussed the difficulties that he had identifying values and that he felt he had lived a life without such values. The repeated weekly values questionnaire may have served as a reminder that his observation on his life had not changed. The

measures were selected after careful and critical consideration to maximise the understating of behavioural activation for this population, which would not have been possible with fewer measures.

Another strength of the design was establishing a baseline, a short questionnaire was used every-other-day to track changes in mood and activation. Using a modified short screen meant that baseline data points could be collected and established in a shorter period of time than using weeks to months of HADS questionnaires, which would have meant prolonging intervention. Whilst data points could be collected over a shorter period of time the process of adapting measures threatens the validity and reliability of the measure. Further, converting the data from the PHQ2 using trendlines and intercepts was not without difficulty as the sensitivity for change in both the HADS and PHQ2 are different. To overcome the changes made to baseline data a triangulation of assessment was used including the conservative dual-criterion method which takes into account trendline from baseline. Therefore, any increase or decrease could still be analysed taking into account behaviour observed prior to intervention.

One potential limitation of the study was the time of year. Several participants took part over Christmas. One participant whose baseline trended to improvement commented that he thought that things had not changed in regard to his mood and that the reported changes on measures were likely accounted for by it being Christmas which they said often gives people a lift in mood. However, Christmas does not always increase people's mood as it can be a polarising period because people with low mood may feel extra pressure to socialise, people may think about loss more, or may not have anyone to share Christmas with.

Therapeutic alliance and its potential effects on outcome need to be considered (Orlinsky et al., 1994) as change may be due to relational

factors. Indeed, variance around common factors can be accredited to relational factors (Wampold & Imel, 2015). During the change interviews participants commented positively on LLO throughout the study, which may be a confounding variable. As a therapeutic relationship measure was not used it is not possible to evaluate the impact of alliance on outcomes.

Participants completed the intervention and study procedures such as measures with no adverse events. One participant withdrew prior to activity scheduling reporting that he did not believe it was possible to improve his mood. Overall, the completion and lack of adverse events suggests that the intervention was appropriately safe and well accepted.

Finally, it is possible that recall and/or social desirability bias (Van de Ven & Huber, 1990) may have occurred. As participants reported their ratings for activities and discussed their diaries, they may have felt pressured to report completion and or benefits. Additionally, change interviews required participants to retrospectively recall their experiences which may have resulted in inconsistencies. In order to mediate potential bias, all diary discussions (completion or non-completion) were viewed as learning opportunities with participants, and change interviews were conducted within two-weeks of the evaluation session.

4.7 Implications for clinical practice and future research

Behavioural activation is a well-established intervention; however, it is used less frequently in isolation. In terms of identifying parsimonious interventions for individuals with degenerative conditions the findings of this study support the use of behavioural activation as a guided self-help approach via telephone-psychotherapy. Benefits of reduced low mood were observed in participants where activation increased, with no adverse effects observed. The design of the study was structured

to replicate potential clinical practice using a structured manualised approach with worksheets and script to provide guided self-help, which increases the ecological validity of the findings. Whist the findings of the study are helpful, it is important to not over- or understate the effectiveness of the intervention due to the sample size and lack of control group to contextualise. The design of the study provides insights into mediators and moderators of therapy which is important because it is necessary to understand what, if anything, creates change. The increase in activities that were positively reinforcing reduced mood. The positive impact may be attractive to individuals and the NHS as the number of sessions and format are comparable to existing services such as IAPT. However, behaviour change was not observed in all cases and future research is needed to understand why behaviour change does not occur in individuals with degenerative conditions and randomised-controlled trials are needed to provide comparative data on group effects and therefore whether behavioural activation for individuals with secondary progressive MS is efficacious. Due to the manualised and scripted approach repeating the intervention in a randomised-controlled trial should be harmonious. As previously discussed, the use of values within the intervention warrants further understanding and would be feasible in a three-arm trial.

5. Personal Reflections

This section offers my personal reflections on the research process including the reasons for conducting research in this area, reflections on the literature, rationale for selecting behavioural activation, methodological considerations, and learning points.

Typically, quantitative research projects do not include a reflective process nor is it common place to include reflections in a critical realist framework. However, as critical realism theorises that a world exists independent of an individual's understanding and that a world exists of subjective interpretations that influence the way individuals experience it (Edwards et al., 2014) it would be helpful to understand how I attempted to balance the perspectives within the study. As I have considered the history, beliefs, and context in which participants live it seems fitting that I consider my own within the same context. Further, clinical psychologists are uniquely placed within the healthcare profession as we are encouraged to be reflective in our practice in order to promote growth and engage in evidenced based practice (McIntosh, 2010).

When I started clinical training, I had a number of ideas that I wanted to consider for my thesis; which I hoped I would be able to link to my previous experiences. I wanted to conduct research with individuals who had neurological conditions and hoped to be able to draw on the considerable experience of the course staff and field supervisors who had expertise in this area. I hoped that continuing to develop my skills within this area would help me apply clinical skills post-training. Based on my experience of working with people who had Parkinson's disease I was aware that there are individuals who experience a number of difficulties in the face of increasing physical difficulty but there was a lack of adapted therapeutic approaches available to them. I discovered

that the course staff had close links and a growing portfolio of research working with people who had MS. I was able to spend time learning about the condition and the challenges individuals face and how many services are set up to support individuals with cognitively driven interventions. The need for the research, and more specifically, effective interventions is high when considering the economic pressures that the NHS faces. Further, as a move toward integrating physical and mental health concepts continues to grow, and research shows the bidirectional effects on mental and physical health outcomes, completing research in this area is important.

Whilst critically evaluating the literature on mental health prevalence in individuals with neurological conditions I found it surprising that despite the vast number of neurological conditions and the varying difficulties including cognitive, emotional, and behavioural changes, there were no specific guidelines relating to supporting mental health difficulties in neurological populations. Instead, NICE guidance suggests referencing the guidelines for supporting people with mental health difficulties who have chronic health difficulties. Despite the lack of specific guidelines, NICE did make recommendations that behavioural activation approaches needed investigating for their effectiveness.

Whilst the study was in its developmental phase I worked with a patient and public involvement panel that consisted of people with secondary progressive MS and their carers. During this time, I was able to consider the applications of a behavioural activation approach and how continued physical decline makes long-term engagement in positively reinforcing activities difficult. Within my clinical work I align myself with the concepts of Acceptance and Commitment Therapy and its application to emotional distress in individuals with physical health difficulties. When considering longer-term changes in cognition

engagement in Acceptance and Commitment Therapy concepts may be difficult but behavioural theory and valued living appeared congruent in its application to a secondary progressive MS population.

When completing a systematic review on behavioural activation approaches for individuals with a neurological condition (Oates et al., 2019) there appeared to be some limited evidence of effectiveness of behavioural activation in reducing depression, though less was known about the impact of behavioural activation on progressive conditions.

When designing the research, I considered the most appropriate approach to answer my research questions. Whilst randomised-controlled trials are gold standard for assessing effectiveness, the MRC guidance for developing effective strategies (Moore et al., 2015) made me consider the importance of demonstrating processes that occur during interventions. The evidence base for process in behavioural activation research is lacking. Therefore, I concluded that the primary importance, was to first show that behavioural activation processes account for changes in depression before considering group comparison research.

Single-case experimental designs use repeated measurement of the process and outcome of interest. Therefore, the measurement strategy needed careful consideration to ensure that we could confidently attribute change to therapy rather than non-therapeutic variables. Initially, I had selected measures with good reliability and validity however in the early design iterations the measures were full length versions. In the process of trying to ensure rigour I had lost contact with the practitioner element of the scientist-practitioner approach, and I had not fully considered the burden and fatigue that completing the high number of questions and questionnaires would cause. People with secondary progressive MS experience fatigue and when people

experience depression, we know that engagement in tasks is difficult and that lack of motivation is common. Thankfully, being able to work with people who have secondary progressive MS and their carers was a valuable opportunity to consider the impact that my initial protocol would have caused, the process also put me in direct contact with my end users and I was able to step back in to a practitioner mindset and empathically consider how to strike the balance between strong methodological approaches that also had the ability to work in practice.

The selection of the behavioural activation manual was something that I reflected on for some time. Eventually, the BATD-R was selected due to its use of values-based activities which was congruent with the idea that as physical health declined, activities could still be identified that were positively reinforcing for them. The literature supporting the use of a five-session model and the additional training video and paper to use the manual meant that I felt skilled in my ability to apply it to the population studied.

I had experience of conducting research within the NHS and completing ethical applications. I knew it was important to start early in order to ensure enough time was available to complete the research. I had not anticipated the amount of time and administration resources that would be involved when working as an individual and not a research team. The research coincided with changes to data protection as it moved to GDPR, also the ethical process changed so that I no longer needed to apply for both university ethics and HRA approval. Unfortunately, I had already started the process for data protection under the old act and applied for university ethics as everything changed. The HRA process felt manageable due to having experienced the process previously but I had not anticipated the effects of recruiting at a site that I did not work for. There was a lack of continuity from HRA approval to site set up which created significant delays and I found

myself trying to balance increasing anxiety and recruiting enough participants.

Based on the literature the recruitment plan seemed sound. The local site team provided information to potential participants, but it is not clear whether there were less individuals reporting with symptoms of low mood and secondary progressive MS or whether promoting the study came with challenges. Fortunately, including the local MS Society groups was of great benefit, but in the future, I would set up the recruitment strategy with the aim to over recruit and use a number of sites.

The approach to analysis was well considered because often single-case experimental designs only use visual analysis with less consideration to effect size and reliable and clinically significant change. I believed that adding these factors alongside a framework analysis provided explanatory power to think about variables and potential factors that contribute to change and facilitated more detailed interpretation of the data. However, on reflection, without a designated primary analysis method the results would have been very difficult to interpret due to the variance in findings.

One thing that I noticed was an ambivalence in my motivation to avoid attrition. During the study I would often formulate participants' motivation for change because one of the critical skills for a clinical psychologist is knowing when to bring about endings. However, as the recruitment process had been challenging, I found myself wanting to support those in the study which may not have been helpful. Specifically, the participant who withdrew frequently sent me emails about the process of the research, asking questions about the questionnaires, or giving me feedback on the Qualtrics system. When I first called him to discuss the study, I called his house phone and it

rang out, I then called his mobile phone which also rang out. I followed up by emailing and saying that I had been unable to leave a voicemail, but I would be happy to call again. The day after I received an email where he chastised me for "not appreciating my audience" and that whilst he had anticipated my call his anxiety had made it difficult for him to answer and that his children can expect the phone to ring beyond 20 times before he answers. I felt very guilty but acknowledged that it may have been difficult and that it was helpful that he had let me know. During his time in the study he said he did not see the point in making any changes and that he knew what his outcomes would be. He often fixated on certain things, for example, he spent each of the sessions retelling one story, which he also told during the change interview with CM. After he withdrew from the study, he continued to email me about difficulties within his life. I found this very challenging, as he had indicated he did not think the sessions could be helpful, but he kept emailing me to discuss things that had annoyed or upset him. There is a line between being a researcher and clinician and at times I found it a hard one to walk. I wanted to support my participant but recognised that if he was not in the study, then I was not his therapist. I thanked him again for his input into the research and suggested that any further support be sought through his GP.

The research process presented a number of opportunities to build on my research skills, from writing journal ready papers, the publication process, designing and analysing studies, and engaging with the administration processes in the NHS. I believe that being able to communicate effectively and use my time efficiently meant that I was able to pursue hold ups rather than leaving them which would have resulted in much longer delays. My confidence has increased in regard to synthesising results, particularly in regard to systematic reviews where working with my supervisors showed me better ways to consolidate results and highlight to a reader what has been found. I

have been very appreciative of the MS community for their passion and engagement in research projects with them commenting that they would like to continue to help support ongoing and upcoming projects in this field. Their commitment to engaging in a project and not knowing whether it would be effective or not is commendable and without their passion this thesis would not have been possible. Despite the difficulties in regard to administration and conducting research within changing services my enthusiasm to continue to contribute to the field is higher than ever.

References

Abramson, L. Y., Seligman, M. E., & Teasdale, J. D. (1978). Learned helplessness in humans: Critique and reformulation. *Journal of Abnormal Psychology, 87*(1), 49-74. https://doi.org/10.1037/0021-843X.87.1.49

Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes, 50*(2), 179-211.

Armento, M. E. A., McNulty, J. K., & Hopko, D. R. (2012). Behavioral activation of religious behaviors (BARB): Randomized trial with depressed college students. *Psychology of Religion and Spirituality, 4*(3), 206-222. https://doi.org/10.1037/a0026405

Azrin, N. H., & Besalel, V. A. (1981). An operant reinforcement method of treating depression. *Journal of Behavior Therapy and Experimental Psychiatry, 12*(2), 145-151.

Backman, C. L., Harris, S. R., Chisholm, J. A. M., & Monette, A. D. (1997). Single-subject research in rehabilitation: a review of studies using AB, withdrawal, multiple baseline, and alternating treatments designs. *Archives of Physical Medicine and Rehabilitation, 78*(10), 1145-1153.

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist, 37*(2), 122-147. https://doi.org/10.1037/0003-066X.37.2.122

Barlow, D. H., Nock, M. K., & Hersen, M. (2008). *Single case experimental designs: Strategies for studying behaviour change* (3rd ed.). Pearson.

Barnwell, A. M., & Kavanagh, D. J. (1997). Prediction of psychological adjustment to multiple sclerosis. *Social Science & Medicine, 45*(3), 411-418. https://doi.org/10.1016/S0277-9536(96)00356-5

Beck, A. T. (1963). Thinking and depression: I. Idiosyncratic content and cognitive distortions. *Archives of General Psychiatry, 9*(4), 324-333.

Beck, A. T. (1964). Thinking and depression: II. Theory and therapy. *Archives of General Psychiatry, 10*(6), 561-571.

Beck, A. T. (1967). *Depression: causes and treatment*. University of Pennsylvania Press.

Beck, A. T., Rush, A. J., Shaw, B. F., & Emery, G. (1979). *Cognitive therapy of depression*. Guilford Press.

Beckner, V., Vella, L., Howard, I., & Mohr, D. C. (2007). Alliance in two telephone-administered treatments: relationship with depression and health outcomes. *Journal of Consulting and Clinical Psychology, 75*(3), 508-512. https://doi.org/10.1037/0022-006x.75.3.508

Bee, P. E., Bower, P., Lovell, K., Gilbody, S., Richards, D., Gask, L., & Roach, P. (2008). Psychotherapy mediated by remote communication technologies: a meta-analytic review. *BMC Psychiatry, 8*(1), 60. https://doi.org/10.1186/1471-244X-8-60

Benedict, R. H., Cookfair, D., Gavett, R., Gunther, M., Munschauer, F., Garg, N., & Weinstock-Guttman, B. (2006). Validity of the

minimal assessment of cognitive function in multiple sclerosis (MACFIMS). *Journal of the International Neuropsychological Society, 12*(4), 549-558.

Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *Journal of Psychosomatic Research, 52*(2), 69-77.

Bloom, M., Fisher, J., & Orme, J. (2003). *Evaluation practitioner: Guidelines for the accountable professional*. Allyn and Bacon

Bonow, J. T., & Follette, W. C. (2009). Beyond values clarification: addressing client values in clinical behavior analysis. *The Behavior Analyst, 32*(1), 69-84. https://doi.org/10.1007/bf03392176

Boyle, M. (2007). The problem with diagnosis. *The psychologist, 20*(5), 290-292. https://thepsychologist.bps.org.uk/volume-20/edition-5/diagnosis-special-issue-part-1-2

Brenes, G. A., Ingram, C. W., & Danhauer, S. C. (2011). Benefits and challenges of conducting psychotherapy by telephone. *Professional Psychology: Research and Practice, 42*(6), 543-549. https://doi.org/10.1037/a0026135

Castonguay, L. G. (2011). Psychotherapy, psychopathology, research and practice: Pathways of connections and integration. *Psychotherapy Research, 21*(2), 125-140. https://doi.org/10.1080/10503307.2011.563250

Center for Substance Abuse Treatment. (1999). Brief cognitive-behavioral therapy. In *Brief interventions and brief therapies for substance abuse* (2012 ed.). Substance Abuse and Mental Health Services Administration. https://www.ncbi.nlm.nih.gov/books/NBK64948/

Chwastiak, L., Ehde, D. M., Gibbons, L. E., Sullivan, M., Bowen, J. D., & Kraft, G. H. (2002). Depressive symptoms and severity of illness in multiple sclerosis: Epidemiologic study of a large community sample. *American Journal of Psychiatry, 159*(11), 1862-1868.

Clarke, H., Rees, A., & Hardy, G. E. (2004). The big idea: Clients' perspectives of change processes in cognitive therapy. *Psychology and Psychotherapy, 77*(Pt 1), 67-89. https://doi.org/10.1348/147608304322874263

Clore, G. L., & Huntsinger, J. R. (2007). How emotions inform judgment and regulate thought. *Trends in Cognitive Sciences, 11*(9), 393-399. https://doi.org/10.1016/j.tics.2007.08.005

Compston, A., & Coles, A. (2008). Multiple sclerosis. *Lancet, 372*(9648), 1502-1517. https://doi.org/10.1016/s0140-6736(08)61620-7

Confavreux, C., & Vukusic, S. (2006). Natural history of multiple sclerosis: a unifying concept. *Brain, 129*(3), 606-616.

Cooper, C. L., Hind, D., Parry, G. D., Isaac, C. L., Dimairo, M., O'Cathain, A., Rose, A., Freeman, J. V., Martin, L., & Kaltenthaler, E. C. (2011). Computerised cognitive behavioural

therapy for the treatment of depression in people with multiple sclerosis: external pilot trial. *Trials, 12*(1), 259.

Coyne, J. C., Thompson, R., & Palmer, S. C. (2002). Marital quality, coping with conflict, marital complaints, and affection in couples with a depressed wife. *Journal of Family Psychology, 16*(1), 26-37.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ, 337*, a1655.

Cuijpers, P., Smit, F., Bohlmeijer, E., Hollon, S. D., & Andersson, G. (2010). Efficacy of cognitive-behavioural therapy and other psychological treatments for adult depression: meta-analytic study of publication bias. *British Journal of Psychiatry, 196*(3), 173-178. https://doi.org/10.1192/bjp.bp.109.066001

Cuijpers, P., Van Straten, A., & Warmerdam, L. (2007). Behavioral activation treatments of depression: A meta-analysis. *Clinincal Psychology Review, 27*(3), 318-326.

Cully, J. A., Paukert, A., Falco, J., & Stanley, M. (2009). Cognitive-behavioral therapy: Innovations for cardiopulmonary patients with depression and anxiety. *Cognitive and Behavioral Practice, 16*(4), 394-407. https://doi.org/10.1016/j.cbpra.2009.04.004

Daughters, S. B., Braun, A. R., Sargeant, M. N., Reynolds, E. K., Hopko, D. R., Blanco, C., & Lejuez, C. W. (2008). Effectiveness of a brief behavioral treatment for inner-city illicit drug users with elevated depressive symptoms: the life enhancement

treatment for substance use (LETS Act!). *Journal of Clinical Psychiatry, 69*(1), 122-129. https://doi.org/10.4088/jcp.v69n0116

David, D., Cristea, I., & Hofmann, S. G. (2018). Why cognitive behavioral therapy is the current gold standard of psychotherapy. *Frontiers in Psychiatry, 9*, 4. https://doi.org/10.3389/fpsyt.2018.00004

Davies, J., Howells, K., & Jones, L. (2007). Evaluating innovative treatments in forensic mental health: A role for single case methodology? *Journal of Forensic Psychiatry & Psychology, 18*(3), 353-367. https://doi.org/10.1080/14789940701443173

Dawson, D., Gresswell, D. M., St Ledger, R., & Moghaddam, N. (2015). Clinical Behaviour Analysis. In D. Dawson & N. Moghaddam (Eds.), *Formulation in action: applying psychological theory to clinical practice*. Walter de Gruyter.

Dimidjian, S., Barrera, M., Jr., Martell, C., Munoz, R. F., & Lewinsohn, P. M. (2011). The origins and current status of behavioral activation treatments for depression. *Annual Review of Clinical Psychology, 7*, 1-38. https://doi.org/10.1146/annurev-clinpsy-032210-104535

Dimidjian, S., Hollon, S. D., Dobson, K. S., Schmaling, K. B., Kohlenberg, R. J., Addis, M. E., Gallop, R., McGlinchey, J. B., Markley, D. K., & Gollan, J. K. (2006). Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. *Journal of Consulting and Clinical Psychology, 74*(4), 658.

Edwards, P. K., O'Mahoney, J., & Vincent, S. (2014). *Studying organizations using critical realism: A practical guide* (Vol. 17). Oxford University Press.

Ehde, D. M., Elzea, J. L., Verrall, A. M., Gibbons, L. E., Smith, A. E., & Amtmann, D. (2015). Efficacy of a telephone-delivered self-management intervention for persons with multiple sclerosis: A randomized controlled trial with a one-year follow-pp. *Archives of Physical Medicine and Rehabilitation, 96*(11), 1945-1958.e1942. https://doi.org/10.1016/j.apmr.2015.07.015

Ekers, D., Richards, D., & Gilbody, S. (2008). A meta-analysis of randomized trials of behavioural treatment of depression. *Psychological Medicine, 38*(5), 611-623. https://doi.org/10.1017/s0033291707001614

Ekers, D., Richards, D., McMillan, D., Bland, J. M., & Gilbody, S. (2011). Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. *British Journal of Psychiatry, 198*(1), 66-72. https://doi.org/10.1192/bjp.bp.110.079111

Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D., & Gilbody, S. (2014). Behavioural Activation for Depression; An Update of Meta-Analysis of Effectiveness and Sub Group Analysis. *PLoS One, 9*(6), e100100. https://doi.org/10.1371/journal.pone.0100100

Elliott, R., & Timulak, L. (2005). Descriptive and interpretive approaches to qualitative research. In J. Miles, & P. Gilbert

(Eds.), *A Handbook of Research Methods for Clinical and Health Psychology* (pp. 147-159). Oxford University Press.

Farrand, P., & Woodford, J. (2015). Effectiveness of cognitive behavioural self-help for the treatment of depression and anxiety in people with long-term physical health conditions: a systematic review and meta-analysis of randomised controlled trials. *Annals of Behavioral Medicine, 49*(4), 579-593. https://doi.org/10.1007/s12160-015-9689-0

Ferster, C. B. (1973). A functional analysis of depression. *American Psychologist, 28*(10), 857-870. https://doi.org/10.1037/h0035605

Ferster, C. B., & Skinner, B. F. (1957). *Schedules of reinforcement*. Prentice-Hall, Inc.

Fisher, W. W., Kelley, M. E., & Lomas, J. E. (2003). Visual aids and structured criteria for improving visual inspection and interpretation of single-case designs. *Journal of Applied Behavior Analysis, 36*(3), 387-406. https://doi.org/10.1901/jaba.2003.36-387

Fitzpatrick, L., Simpson, J., & Smith, A. (2010). A qualitative analysis of mindfulness-based cognitive therapy (MBCT) in Parkinson's disease. *Psychology and Psychotherapy, 83*(Pt 2), 179-192. https://doi.org/10.1348/147608309x471514

Fletcher, J., Bower, P., Gask, L., Richards, D., & Saunders, T. (2006). *Primary care services for depression: a guide to best practice*. Care Services Improvement Partnership.

Frederiksen, L. W. (1975). Treatment of ruminative thinking by self-monitoring. *Journal of Behavior Therapy and Experimental Psychiatry, 6*(3), 258-259.

Freud, A. (1992). *The ego and the mechanisms of defence*. Routledge.

Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology, 13*, 117. https://doi.org/10.1186/1471-2288-13-117

Galeazzi, G. M., Ferrari, S., Giaroli, G., Mackinnon, A., Merelli, E., Motti, L., & Rigatelli, M. (2005). Psychiatric disorders and depression in multiple sclerosis outpatients: impact of disability and interferon beta therapy. *Neurological Sciences, 26*(4), 255-262. https://doi.org/10.1007/s10072-005-0468-8

Gallagher, D., Thompson, L., Baffa, G., Piatt, C., Ringering, L., & Stone, V. (Eds.). (1981). *Depression in the elderly: A behavioral treatment manual*. University of Southern California Press.

Gar, N. S., & Hudson, J. L. (2009). Changes in maternal expressed emotion toward clinically anxious children following cognitive behavioral therapy. *Journal of Experimental Child Psychology, 104*(3), 346-352. https://doi.org/10.1016/j.jecp.2009.06.001

Gawrysiak, M., Nicholas, C., & Hopko, D. R. (2009). Behavioral activation for moderately depressed university students:

Randomized controlled trial. *Journal of Counseling Psychology, 56*(3), 468-475. https://doi.org/10.1037/a0016383

Geddes, J., Fear, J., Tennant, A., Pickering, A., Hillman, M., & Chamberlain, M. A. (1996). Prevalence of self reported stroke in a population in northern England. *Journal of Epidemiology & Community Health, 50*(2), 140-143.

Gilden, D. H. (2005). Infectious causes of multiple sclerosis. *The Lancet Neurology, 4*(3), 195-202.

Gottlieb, D. A., & Begej, E. L. (2014). Principles of Pavlovian conditioning: Description, content, function. In F. K. McSweeney & E. S. Murphy (Eds.), *The Wiley Blackwell handbook of operant classical conditioning* (pp. 3-25). Wiley Blackwell.

Graf, M. G. (1977). A mood-related activities schedule for the treatment of depression. *Dissertation Abstracts International, 38*(3-B), 1400–1401.

Grant, A., Treweek, S., Dreischulte, T., Foy, R., & Guthrie, B. (2013). Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials, 14*(1), 15.

Greenberg, J. R., & Mitchell, S. A. (1983). *Object relations in psychoanalytic theory*. Harvard University Press.

Gross, A. E., & McMullen, P. A. (1983). Models of the help-seeking process. In B. M. DePaulo, A. Nadler, & J. D. Fisher (Eds.), *New*

directions in helping: Help-seeking (Vol. 2, pp. 45–70). Academic Press.

Gulliver, A., Griffiths, K. M., Christensen, H., & Brewer, J. L. (2012). A systematic review of help-seeking interventions for depression, anxiety and general psychological distress. *BMC Psychiatry, 12*, 81. https://doi.org/10.1186/1471-244x-12-81

Hailey, D., Roine, R., Ohinmaa, A., & Dennett, L. (2011). Evidence of benefit from telerehabilitation in routine care: a systematic review. *Journal of Telemedicine and Telecare, 17*(6), 281-287. https://doi.org/10.1258/jtt.2011.101208

Hakim, E. A., Bakheit, A. M. O., Bryant, T. N., Roberts, M. W. H., McIntosh-Michaelis, S. A., Spackman, A. J., Martin, J. P., & McLellan, D. L. (2000). The social impact of multiple sclerosis - a study of 305 patients and their relatives. *Disability and Rehabilitation, 22*(6), 288-293. https://doi.org/10.1080/096382800296755

Harandi, T. F., Taghinasab, M. M., & Nayeri, T. D. (2017). The correlation of social support with mental health: A meta-analysis. *Electronic Physician Journal, 9*(9), 5212-5222. https://doi.org/10.19082/5212

Harden, C. L. (2002). The co-morbidity of depression and epilepsy epidemiology, etiology, and treatment. *Neurology, 59*(6 suppl 4), S48-S55.

Hart, Y. M., Sander, J. W., Johnson, A. L., & Shorvon, S. D. (1990). National General Practice Study of epilepsy: Recurrence after a

first seizure. *Lancet, 336*(8726), 1271-1274. https://doi.org/10.1016/0140-6736(90)92960-p

Hayes, S. C., Barnes-Holmes, D., & Roche, B. (Eds.). (2001). *Relational frame theory: A post-Skinnerian account of human language and cognition.* Kluwer Academic/Plenum Publishers.

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (1999). *Acceptance and commitment therapy: An experiential approach to behavior change*. The Guilford Press.

Health Research Authority. (2017). *Public involvement in applications to the Health Research Authority Research Ethics Service*. https://www.hra.nhs.uk/documents/1331/public-involvement-applications-hra.pd

Henry, P. C. (2005). Life stresses, explanatory style, hopelessness, and occupational class. *International Journal of Stress Management, 12*(3), 241-256. https://doi.org/10.1037/1072-5245.12.3.241

Herrnstein, R. J. (1970). On the law of effect. *Journal of the Experimental Analysis of Behavior, 13*(2), 243-266. https://doi.org/10.1901/jeab.1970.13-243

Hind, D., Cotter, J., Thake, A., Bradburn, M., Cooper, C., Isaac, C., & House, A. (2014). Cognitive behavioural therapy for the treatment of depression in people with multiple sclerosis: a systematic review and meta-analysis. *BMC Psychiatry, 14*(1), 5.

Hind, D., Kaklamanou, D., Beever, D., Webster, R., Lee, E., Barkham, M., & Cooper, C. (2016). The assessment of depression in people with multiple sclerosis: a systematic review of psychometric validation studies. *BMC Psychiatry, 16*(1), 278.

Hind, D., O'Cathain, A., Cooper, C. L., Parry, G. D., Isaac, C. L., Rose, A., Martin, L., & Sharrack, B. (2010). The acceptability of computerised cognitive behavioural therapy for the treatment of depression in people with chronic physical disease: a qualitative study of people with multiple sclerosis. *Psychology and Health, 25*(6), 699-712.

Hiroto, D. S., & Seligman, M. E. (1975). Generality of learned helplessness in man. *Journal of Personality and Social Psychology, 31*(2), 311-327. https://doi.org/10.1037/h0076270

Holtzer, R., Scarmeas, N., Wegesin, D. J., Albert, M., Brandt, J., Dubois, B., Hadjigeorgiou, G. M., & Stern, Y. (2005). Depressive symptoms in Alzheimer's disease: natural course and temporal relation to function and cognitive status. *Journal of the American Geriatrics Society, 53*(12), 2083-2089.

Honarmand, K., & Feinstein, A. (2009). Validation of the Hospital Anxiety and Depression Scale for use with multiple sclerosis patients. *Multiple Sclerosis Journal, 15*(12), 1518-1524.

Hopko, D. R., Lejuez, C. W., LePage, J. P., Hopko, S. D., & McNeil, D. W. (2003). A brief behavioral activation treatment for depression. A randomized pilot trial within an inpatient psychiatric hospital. *Behavior Modification, 27*(4), 458-469. https://doi.org/10.1177/0145445503255489

Horner, R., & Spaulding, S. (2010). Single-case research designs. In N. J. Salkind (Ed.), *Encyclopedia of research design* (pp. 1386–1394). Sage.

Jacobson, N. S., Dobson, K. S., Truax, P. A., Addis, M. E., Koerner, K., Gollan, J. K., Gortner, E., & Prince, S. E. (1996). A component analysis of cognitive-behavioral treatment for depression. *Journal of Consulting and Clinical Psychology, 64*(2), 295-304.

Jacobson, N. S., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*(1), 12-19. https://doi.org/10.1037//0022-006x.59.1.12

Janzen, W., Turpin, K. V. L., Warren, S. A., Marrie, R. A., & Warren, K. G. (2013). Change in the health-related quality of life of multiple sclerosis patients over 5 years. *International Journal of MS Care, 15*(1), 46-53. https://doi.org/10.7224/1537-2073.2012-020

Johansson, T., & Wild, C. (2011). Telerehabilitation in stroke care: a systematic review. *Journal of Telemedicine and Telecare, 17*(1), 1-6. https://doi.org/10.1258/jtt.2010.100105

Jones, C. A., Pohar, S. L., Warren, S., Turpin, K. V., & Warren, K. G. (2008). The burden of multiple sclerosis: a community health survey. *Health and Quality of Life Outcomes, 6*, 1. https://doi.org/10.1186/1477-7525-6-1

Jones, K. H., Ford, D. V., Jones, P. A., John, A., Middleton, R. M., Lockhart-Jones, H., Osborne, L. A., & Noble, J. G. (2012). A large-scale study of anxiety and depression in people with multiple sclerosis: A survey via the web portal of the UK MS Register. *PLoS One, 7*(7), e41910. https://doi.org/10.1371/journal.pone.0041910

Jorge, R. E., Robinson, R. G., Moser, D., Tateno, A., Crespo-Facorro, B., & Arndt, S. (2004). Major depression following traumatic brain injury. *Archives of General Psychiatry, 61*(1), 42-50. https://doi.org/10.1001/archpsyc.61.1.42

Kanfer, F. H. (1970). Self-monitoring: Methodological limitations and clinical applications. *Journal of Consulting and Clinical Psychology, 35*(2), 148-152. https://doi.org/10.1037/h0029874

Kanter, J. W., Baruch, D. E., & Gaynor, S. T. (2006). Acceptance and commitment therapy and behavioral activation for the treatment of depression: Description and comparison. *The Behavior Analyst, 29*(2), 161-185.

Kanter, J. W., Busch, A. M., & Rusch, L. C. (2009). *Behavioral activation: Distinctive features*. Routledge Press.

Kanter, J. W., Manos, R. C., Bowe, W. M., Baruch, D. E., Busch, A. M., & Rusch, L. C. (2010). What is behavioral activation?: A review of the empirical literature. *Clinical Psychology Review, 30*(6), 608-620.

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. (2012). *Behavioral Activation for Depression Scale*

(BADS)(Long and Short Form). Measurement Instrument Database for the Social Science. Retrieved 1st March from http://www.midss.org/content/behavioral-activation-depression-scale-bads-long-and-short-form

Kanter, J. W., Santiago-Rivera, A. L., Rusch, L. C., Busch, A. M., & West, P. (2010). Initial outcomes of a culturally adapted behavioral activation for Latinas diagnosed with depression at a community clinic. *Behavior Modification, 34*(2), 120-144. https://doi.org/10.1177/0145445509359682

Katon, W. J. (2003). Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. *Biological Psychiatry, 54*(3), 216-226. https://doi.org/10.1016/S0006-3223(03)00273-7

Kendler, K. S., Karkowski, L. M., & Prescott, C. A. (1999). Causal relationship between stressful life events and the onset of major depression. *American Journal of Psychiatry, 156*(6), 837-841. https://doi.org/10.1176/ajp.156.6.837

Kendler, K. S., Kessler, R. C., Walters, E. E., MacLean, C., Neale, M. C., Heath, A. C., & Eaves, L. J. (1995). Stressful life events, genetic liability, and onset of an episode of major depression in women. *American Journal of Psychiatry, 152*(6), 833-842. https://doi.org/10.1176/ajp.152.6.833

Kessler, R. C., Berglund, P., Demler, O., Jin, R., Koretz, D., Merikangas, K. R., Rush, A. J., Walters, E. E., & Wang, P. S. (2003). The epidemiology of major depressive disorder: Results from the national comorbidity survey replication (NCS-R).

JAMA, 289(23), 3095-3105. https://doi.org/10.1001/jama.289.23.3095

Kessler, R. C., Berglund, P., Demler, O., Jin, R., Merikangas, K. R., & Walters, E. E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry, 62*(6), 593-602.

Kessler, R. C., Chiu, W. T., Demler, O., & Walters, E. E. (2005). Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry, 62*(6), 617-627.

Khan, F., Turner-Stokes, L., Ng, L., & Kilpatrick, T. (2007). Multidisciplinary rehabilitation for adults with multiple sclerosis. *The Cochrane Database of Systematic Reviews*(2), Cd006036. https://doi.org/10.1002/14651858.CD006036.pub2

Khurana, V., Sharma, H., & Medin, J. (2018). Estimated prevalence of secondary progressive multiple sclerosis in the USA and Europe: results from a systematic literature search. *Neurology, 90*(15 Supplement), P2.380.

Kibler, J. (2011). Cognitive Schemas. In S. Goldstein & J. A. Naglieri (Eds.), *Encyclopedia of Child Behavior and Development* (pp. 382-382). Springer US. https://doi.org/10.1007/978-0-387-79061-9_608

Kidd, T., Carey, N., Mold, F., Westwood, S., Miklaucich, M., Konstantara, E., Sterr, A., & Cooke, D. (2017). A systematic review of the effectiveness of self-management interventions in

people with multiple sclerosis at improving depression, anxiety and quality of life. *PLoS One, 12*(10), e0185931. https://doi.org/10.1371/journal.pone.0185931

Kim, E., Lauterbach, E. C., Reeve, A., Arciniegas, D. B., Coburn, K. L., Mendez, M. F., Rummans, T. A., & Coffey, E. C. (2007). Neuropsychiatric complications of traumatic brain injury: A critical review of the literature. *Journal of Neuropsychiatry and Clinical Neurosciences, 19*(2), 106-127. https://doi.org/10.1176/jnp.2007.19.2.106

Kings Fund. (2012). *Long-term conditions and mental health: The cost of comorbidities*. Kings Fund.

Klein, M. J., & Elliott, R. (2006). Client accounts of personal change in process–experiential psychotherapy: A methodologically pluralistic approach. *Psychotherapy Research, 16*(1), 91-105.

Knirsch, P. (2015). *Measuring values and committed action with the Engaged Living Scale (ELS): psychometric evaluation in populations with minor depression and chronic pain (Master's thesis)* https://pdfs.semanticscholar.org/3a21/4a99db5cb6ddecd57c1b36a68f6434872b8a.pdf?_ga=2.81152919.164475949.1586437813-959969512.1580651465

Kobelt, G., Eriksson, J., Phillips, G., & Berg, J. (2017). The burden of multiple sclerosis 2015: Methods of data collection, assessment and analysis of costs, quality of life and symptoms. *Multiple Sclerosis Journal, 23*(2_suppl), 4-16.

Kratochwill, T., Hitchcock, J., Horner, R., Levin, J. R., Odom, S., Rindskopf, D., & Shadish, W. (2010). *Single-case designs technical documentation*. http://ies.ed.gov/ncee/wwc/pdf/wwc_scd.pdf.

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2003). The Patient Health Questionnaire-2: Validity of a two-item depression screener. *Medical Care, 41*(11), 1284-1292.

Larun, L., Brurberg, K. G., Odgaard-Jensen, J., & Price, J. R. (2015). Exercise therapy for chronic fatigue syndrome. *Cochrane Database of Systematic Reviews*(2). https://doi.org/10.1002/14651858.CD003200.pub3

Lassmann, H., Bruck, W., & Lucchinetti, C. (2001). Heterogeneity of multiple sclerosis pathogenesis: Implications for diagnosis and therapy. *Trends in Molecular Medicine, 7*(3), 115-121.

Latner, J. D., & Wilson, G. T. (2002). Self-monitoring and the assessment of binge eating. *Behavior Therapy, 33*(3), 465-477.

Leach, L. S., & Christensen, H. (2006). A systematic review of telephone-based interventions for mental disorders. *Journal of Telemedicine and Telecare, 12*(3), 122-129. https://doi.org/10.1258/135763306776738558

Lejuez, C. W., Hopko, D. R., Acierno, R., Daughters, S. B., & Pagoto, S. L. (2011). Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. *Behavior Modification, 35*(2), 111-161.

Lejuez, C. W., Hopko, D. R., & Hopko, S. D. (2001). A brief behavioral activation treatment for depression. Treatment manual. *Behavior Modification, 25*(2), 255-286. https://doi.org/10.1177/0145445501252005

Lenz, A. S. (2013). Calculating effect size in single-case research : A comparison of nonoverlap methods. *Measurement and Evaluation in Counseling and Development, 46*, 64.

Lewinsohn, P. M. (1974). A behavioral approach to depression. *Essential Papers on Depression*, 150-172.

Lewinsohn, P. M., Biglan, A., & Zeiss, A. M. (1976). Behavioral treatment of depression. In P. O. Davidson (Ed.), *Behavioral management of anxiety, depression and pain* (pp. 91-146). Brunner/Mazel.

Lewinsohn, P. M., & Libet, J. (1972). Pleasant events, activity schedules, and depressions. *Journal of Abnormal Psychology, 79*(3), 291.

Lewinsohn, P. M., Munoz, R. F., Youngren, M. A., & Zeiss, A. M. (1986). *Control your depression*. Prentice Hall.

Lewinsohn, P. M., & Shaffer, M. (1971). Use of home observations as an integral part of the treatment of depression: Preliminary report and case studies. *Journal of Consulting and Clinical Psychology, 37*(1), 87-94. https://doi.org/10.1037/h0031297

Lewis, C., Pearce, J., & Bisson, J. I. (2012). Efficacy, cost-effectiveness and acceptability of self-help interventions for anxiety disorders: systematic review. *British Journal of*

Psychiatry, 200(1), 15-21. https://doi.org/10.1192/bjp.bp.110.084756

Löwe, B., Kroenke, K., & Gräfe, K. (2005). Detecting and monitoring depression with a two-item questionnaire (PHQ-2). *Journal of Psychosomatic Research, 58*(2), 163-171.

Lublin, F. D., Reingold, S. C., Cohen, J. A., Cutter, G. R., Sørensen, P. S., Thompson, A. J., Wolinsky, J. S., Balcer, L. J., Banwell, B., Barkhof, F., Bebo, B., Jr., Calabresi, P. A., Clanet, M., Comi, G., Fox, R. J., Freedman, M. S., Goodman, A. D., Inglese, M., Kappos, L., Kieseier, B. C., Lincoln, J. A., Lubetzki, C., Miller, A. E., Montalban, X., O'Connor, P. W., Petkau, J., Pozzilli, C., Rudick, R. A., Sormani, M. P., Stüve, O., Waubant, E., & Polman, C. H. (2014). Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology, 83*(3), 278-286. https://doi.org/10.1212/wnl.0000000000000560

Luszczynska, A., & Schwarzer, R. (2005). Social cognitive theory. In M. Conner & P. Norman (Eds.), *Predicting health behaviour* (pp. 127–169). Open University Press.

Ma, H. H. (2006). An alternative method for quantitative synthesis of single-subject researches: Percentage of data points exceeding the median. *Behavior Modification, 30*(5), 598-617. https://doi.org/10.1177/0145445504272974

Mackenzie, I. S., Morant, S. V., Bloomfield, G. A., MacDonald, T. M., & O'Riordan, J. (2014). Incidence and prevalence of multiple sclerosis in the UK 1990-2010: a descriptive study in the General Practice Research Database. *Journal of Neurology,*

Neurosurgery, and Psychiatry, 85(1), 76-84. https://doi.org/10.1136/jnnp-2013-305450

MacPherson, L., Tull, M. T., Matusiewicz, A. K., Rodman, S., Strong, D. R., Kahler, C. W., Hopko, D. R., Zvolensky, M. J., Brown, R. A., & Lejuez, C. W. (2010). Randomized controlled trial of behavioral activation smoking cessation treatment for smokers with elevated depressive symptoms. *Journal of Consulting and Clinical Psychology, 78*(1), 55-61. https://doi.org/10.1037/a0017939

Maier, S. F., & Seligman, M. E. P. (2016). Learned helplessness at fifty: Insights from neuroscience. *Psychological Review, 123*(4), 349-367. https://doi.org/10.1037/rev0000033

Manos, R. C., Kanter, J. W., & Luo, W. (2011). The behavioral activation for depression scale-short form: Development and validation. *Behavior Therapy, 42*(4), 726-739. https://doi.org/10.1016/j.beth.2011.04.004

Martell, C. R., Addis, M. E., & Jacobson, N. S. (2001). *Depression in context: Strategies for guided action*. W.W. Norton.

Martell, C. R., Dimidjian, S., & Herman-Dunn, R. (2010). *Behavioral activation for depression: A clinicians guide*. The Guilford Press.

Mazzucchelli, T., Kane, R., & Rees, C. (2009). Behavioral activation treatments for depression in adults: A meta-analysis and review. *Clinical Psychology: Science and Practice, 16*(4), 383-411. https://doi.org/10.1111/j.1468-2850.2009.01178.x

McFall, R. M. (1970). Effects of self-monitoring on normal smoking behavior. *Journal of Consulting and Clinical Psychology, 35*(2), 135-142. https://doi.org/10.1037/h0030087

McIntosh, P. (2010). *Action research and reflective practice: Creative and visual methods to facilitate reflection and learning*. Routledge.

McLean, P. D. (1976). Decision-making in the behavioral management of depression. In P. O. Davidson (Ed.), *Behavioral management of anxiety, depression and pain* (pp. 54−90). Brunner/Mazel.

McMillan, T., & Greenwood, R. (1991). *Rehabilitation programmes for the brain injured adult: Current practice and future options in the UK*. Department of Health.

Millefiorini, E., Padovani, A., Pozzilli, C., Loriedo, C., Bastianello, S., Buttinelli, C., Piero, V., & Fieschi, C. (1992). Depression in the early phase of MS: influence of functional disability, cognitive impairment and brain abnormalities. *Acta Neurologica Scandinavica, 86*(4), 354-358.

Mohr, D. C., & Cox, D. (2001, Apr). Multiple sclerosis: Empirical literature for the clinical health psychologist. *Journal of Clinical Psychology, 57*(4), 479-499. https://doi.org/10.1002/jclp.1042

Mohr, D. C., Likosky, W., Bertagnolli, A., Goodkin, D. E., Van Der Wende, J., Dwyer, P., & Dick, L. P. (2000). Telephone-administered cognitive–behavioral therapy for the treatment of depressive symptoms in multiple sclerosis. *Journal of Consulting and Clinical Psychology, 68*(2), 356.

Mohr, D. C., Vella, L., Hart, S., Heckman, T., & Simon, G. (2008). The effect of telephone-administered psychotherapy on symptoms of depression and attrition: A meta-analysis. *Clinical Psychology: Science and Practice, 15*(3), 243-253. https://doi.org/10.1111/j.1468-2850.2008.00134.x

Monroe, S. M., Rohde, P., Seeley, J. R., & Lewinsohn, P. M. (1999). Life events and depression in adolescence: relationship loss as a prospective risk factor for first onset of major depressive disorder. *Journal of Abnormal Psychology, 108*(4), 606-614. https://doi.org/10.1037//0021-843x.108.4.606

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D., & Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ, 350*, h1258. https://doi.org/10.1136/bmj.h1258

Morgan, A. J., & Jorm, A. F. (2008). Self-help interventions for depressive disorders and depressive symptoms: A systematic review. *Annals of General Psychiatry, 7*(1), 13.

Morgan, D. L., & Morgan, R. K. (2008). *Single-case research methods for the behavioral and health sciences*. Sage publications.

Morley, S. (2018). *Single-case methods in clinical psychology: A practical guide*. Routledge.

Morse, J. M. (1991). Approaches to qualitative-quantitative methodological triangulation. *Nursing Research, 40*(2), 120-123.

Motl, R. W., McAuley, E., Snook, E. M., & Gliottoni, R. C. (2009). Physical activity and quality of life in multiple sclerosis: Intermediary roles of disability, fatigue, mood, pain, self-efficacy and social support. *Psychology, Health & Medicine, 14*(1), 111-124.

Moussavi, S., Chatterji, S., Verdes, E., Tandon, A., Patel, V., & Ustun, B. (2007). Depression, chronic diseases, and decrements in health: results from the World Health Surveys. *Lancet, 370*(9590), 851-858. https://doi.org/10.1016/s0140-6736(07)61415-9

MS Society. (2018a). *MS in the UK: How many people have MS in the UK?* Retrieved 24th July from https://www.mssociety.org.uk/care-and-support/resources-and-publications/publications-search/ms-in-the-uk

MS Society. (2018b). *MS Society Research Strategy 2018-22*. https://www.mssociety.org.uk/research/explore-our-research/our-research-priorities

MS Trust. (2018). *Causes of MS*. Retrieved 18th September from https://www.mstrust.org.uk/about-ms/what-ms/causes-ms?utm_medium=ppc&utm_source=adwords&utm_campaign=SS+%7C+Search+%7C+Information&utm_term=multiple%20sclerosis%20cause&hsa_acc=6635963470&hsa_src=g&hsa_grp=2020950197&hsa_kw=multiple%20sclerosis%20cause&hsa_ver=3&hsa_tgt=kwd-552696337&hsa_mt=e&hsa_ad=293324122936&hsa_net=adwords&hsa_cam=45961817&gclid=EAIaIQobChMIz7_Kgo7b5AIVhMjeCh1LJw3LEAAYASAAEgLk6fD_BwE

Mullins, L. L., Cote, M. P., Fuemmeler, B. F., Jean, V. M., Beatty, W. W., & Paul, R. H. (2001). Illness intrusiveness, uncertainty, and distress in individuals with multiple sclerosis. *Rehabilitation Psychology, 46*(2), 139-153. https://doi.org/10.1037/0090-5550.46.2.139

Muris, P. (2002). Relationships between self-efficacy and symptoms of anxiety disorders and depression in a normal adolescent sample. *Personality and Individual Differences, 32*(2), 337-348. https://doi.org/https://doi.org/10.1016/S0191-8869(01)00027-7

Murphy, E. S., & Lupfer, G. J. (2014). Basic principles of operant conditioning. In *The Wiley Blackwell handbook of operant and classical conditioning.* (pp. 167-194). Wiley-Blackwell. https://doi.org/10.1002/9781118468135.ch8

National Collaborating Centre for Mental Health, & National Institute for Health Clinical Excellence. (2010). *Depression in adults with a chronic physical health problem: treatment and management*. British Psychological Society and the Royal College of Psychiatrists.

National Institute for Health and Care Excellence. (2006). *Computerised cognitive behaviour therapy for depression and anxiety, (Technology appraisal guidance, TA97)*. Retrieved 26/2/18 from https://www.nice.org.uk/guidance/ta97

National Institute for Health and Care Excellence. (2007). *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management*. Retrieved 20th

July from https://www.nice.org.uk/guidance/cg53/chapter/introduction

National Institute for Health and Care Excellence. (2009). *Depression in adults with a chronic physical health problem: recognition and management. (Clinical guideline, CG91)*. Retrieved 27/02/2018 from https://www.nice.org.uk/guidance/cg91

National Institute for Health and Care Excellence. (2014). *Multiple sclerosis in adults: management Clinical guideline [CG186]*. Retrieved 22nd September from https://www.nice.org.uk/guidance/cg186/

National Institute for Health and Care Excellence. (2015). *Depression*. Retrieved 18th September from https://cks.nice.org.uk/depression#!backgroundSub

National Institute for Health and Care Excellence. (2017). *Computerised cognitive behaviour therapy for depression and anxiety*. https://www.nice.org.uk/guidance/ta97/documents/final-appraisal-determination-depression-and-anxiety-computerised-cognitive-behaviour-therapy-ccbt-review2

National Institute for Health Research. (2014). *Patient and public involvement in health and social care research: A handbook for researchers*. Retrieved 7th March from https://www.nihr.ac.uk/about-us/CCF/funding/how-we-can-help-you/RDS-PPI-Handbook-2014-v*-FINAL.pdf

National Multiple Sclerosis Society. (no date). *Secondary progressive MS (SPMS)*. Retrieved 18th September from

https://www.nationalmssociety.org/What-is-MS/Types-of-MS/Secondary-progressive-MS

Neurological Alliance. (2003). *Neuro numbers: a brief review of the numbers of people in the UK with a neurological condition*. Neurological Alliance.

NHS England. *Neurological conditions*. Retrieved 20th July from https://www.england.nhs.uk/ourwork/ltc-op-eolc/ltc-eolc/our-work-on-long-term-conditions/si-areas/neurological/

Nicholl, C. R., Lincoln, N. B., Francis, V. M., & Stephan, T. F. (2001). Assessment of emotional problems in people with multiple sclerosis. *Clinical Rehabilitation, 15*(6), 657-668.

Oates, L. L., Moghaddam, N., Evangelou, N., & das Nair, R. (2019). Behavioural activation treatment for depression in individuals with neurological conditions: a systematic review. *Clinical Rehabilitation, 34*(3), 310-319. https://doi.org/https://doi.org/10.1177/0269215519896404

Orlinsky, D. E., Grawe, K., & Parks, B. K. (1994). Process and outcome in psychotherapy. In A. Bergin & S. Grafield (Eds.), *Handbook of psychotherapy and behaviour change* (4th ed.). Wiley.

Outhwaite, W. (1987). Realism and social science. In *New Philosophies of Social Science* (pp. 45-60). Springer.

Oxfordshire Community Stroke Project. (1983). Incidence of stroke in Oxfordshire: first year's experience of a community stroke register. *BMJ*, 713-717.

Parkinson, S., Eatough, V., Holmes, J., Stapley, E., & Midgley, N. (2016). Framework analysis: A worked example of a study exploring young people's experiences of depression. *Qualitative Research in Psychology, 13*(2), 109-129. https://doi.org/10.1080/14780887.2015.1119228

Parkinson's UK. (2018). *The incidence and prevalence of Parkinson's in the UK: Results from the Clinical Practice Research Datalink Summary report*. Parkinson's UK. https://www.parkinsons.org.uk/sites/default/files/2018-01/CS2960%20Incidence%20and%20prevalence%20report%20branding%20summary%20report.pdf

Patten, S. B., Beck, C. A., Williams, J. V., Barbui, C., & Metz, L. M. (2003). Major depression in multiple sclerosis: A population-based perspective. *Neurology, 61*(11), 1524-1527.

Pavlov, I. P. (1902). *The work of the digestive glands*. Griffin.

Peterson, C., & Seligman, M. E. (1984). Causal explanations as a risk factor for depression: Theory and evidence. *Psychological Review, 91*(3), 347-374. https://doi.org/10.1037/0033-295X.91.3.347

Petry, N. M. (2011). Contingency management: What it is and why psychiatrists should want to use it. *Psychiatrist, 35*(5), 161-163. https://doi.org/10.1192/pb.bp.110.031831

Plumb, J. C., Stewart, I., Dahl, J., & Lundgren, T. (2009). In search of meaning: Values in modern clinical behavior analysis. *The*

Behavior Analyst, 32(1), 85-103. https://doi.org/10.1007/bf03392177

Price, A., Rayner, L., Okon-Rocha, E., Evans, A., Valsraj, K., Higginson, I. J., & Hotopf, M. (2011). Antidepressants for the treatment of depression in neurological disorders: A systematic review and meta-analysis of randomised controlled trials. *Journal of Neurology, Neurosurgery & Psychiatry, 82*(8), 914. https://doi.org/10.1136/jnnp.2010.230862

Prince, M., Knapp, M., Guerchet, M., McCrone, P., Prina, M., Comas-Herrera, A., Wittenberg, R., Adelaja, B., Hu, B., King, D., Rehill, A., & Salimkumar, D. (2014). *Dementia UK: Update*. Alzheimer's Society. https://www.alzheimers.org.uk/sites/default/files/migrate/downloads/dementia_uk_update.pdf

Proctor, B. J., Moghaddam, N., Vogt, W., & das Nair, R. (2018). Telephone psychotherapy in multiple sclerosis: A systematic review and meta-analysis. *Rehabilitation Psychology, 63*(1), 16-28. https://doi.org/10.1037/rep0000182

Quelhas, R., & Costa, M. (2009). Anxiety, depression, and quality of life in Parkinson's disease. *The Journal of Neuropsychiatry and Clinical Neurosciences, 21*(4), 413-419.

Rassafiani, M., & Sahaf, R. (2010). Single case experimental design: An overview. *International Journal of Therapy and Rehabilitation, 17*(6), 285-289.

Ratajska, A., Zurawski, J., Healy, B., & Glanz, B. I. (2019). Computerized cognitive behavioral therapy for treatment of

depression in multiple sclerosis: A narrative review of current findings and future directions. *International Journal of MS Care, 21*(3), 113-123. https://doi.org/10.7224/1537-2073.2017-094

Rehm, L. P. (1977). A self-control model of depression. *Behavior Therapy, 8*(5), 787-804.

Rejdak, K., Jackson, S., & Giovannoni, G. (2010). Multiple sclerosis: a practical overview for clinicians. *British Medical Bulletin, 95*(1), 79-104.

Richards, D., & Richardson, T. (2012). Computer-based psychological treatments for depression: a systematic review and meta-analysis. *Clinical Psychology Review, 32*(4), 329-342. https://doi.org/10.1016/j.cpr.2012.02.004

Richards, D. A., Ekers, D., McMillan, D., Taylor, R. S., Byford, S., Warren, F. C., Barrett, B., Farrand, P. A., Gilbody, S., Kuyken, W., O'Mahen, H., Watkins, E. R., Wright, K. A., Hollon, S. D., Reed, N., Rhodes, S., Fletcher, E., & Finning, K. (2016). Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. *The Lancet, 388*(10047), 871-880. https://doi.org/10.1016/S0140-6736(16)31140-0

Rickards, H. (2006). Depression in neurological disorders: an update. *Current Opinion in Psychiatry, 19*(3), 294-298.

Rizzo, M., Creed, F., Goldberg, D., Meader, N., & Pilling, S. (2011). A systematic review of non-pharmacological treatments for depression in people with chronic physical health problems.

Journal of Psychosomatic Research, 71(1), 18-27. https://doi.org/10.1016/j.jpsychores.2011.02.011

Roane, H. S., Fisher, W. W., & Carr, J. E. (2016). Applied behavior analysis as treatment for autism spectrum disorder. *The Journal of Pediatrics, 175*, 27-32. https://doi.org/10.1016/j.jpeds.2016.04.023

Sadovnick, A. D., Remick, R. A., Allen, J., Swartz, E., Yee, I. M. L., Eisen, K., Farquhar, R., Hashimoto, S. A., Hooge, J., Kastrukoff, L. F., Morrison, W., Nelson, J., Oger, J., & Paty, D. W. (1996). Depression and multiple sclerosis. *Neurology, 46*(3), 628-632. https://doi.org/10.1212/wnl.46.3.628

Seligman, M. E. (1972). Learned helplessness. *Annual Review of Medicine, 23*(1), 407-412.

Seligman, M. E. (1975). *Helplessness: On depression, development, and death*. W. H. Freeman.

Seligman, M. E., & Maier, S. F. (1967). Failure to escape traumatic shock. *Journal of Experimental Psychology, 74*(1), 1-9. https://doi.org/10.1037/h0024514

Shaw, B. F. (1977). Comparison of cognitive therapy and behavior therapy in the treatment of depression. *Journal of Consulting and Clinical Psychology, 45*(4), 543-551. https://doi.org/10.1037//0022-006x.45.4.543

Skinner, B. F. (1948). 'Superstition' in the pigeon. *Journal of Experimental Psychology, 38*(2), 168-172. https://doi.org/10.1037/h0055873

Skinner, B. F. (1953). *Science and human behavior*. Simon and Schuster.

Skinner, B. F. (1974). *About Behaviourism*. Random House Inc.

Skokou, M., Soubasi, E., & Gourzis, P. (2012). Depression in multiple sclerosis: A review of assessment and treatment approaches in adult and pediatric populations. *ISRN Neurology, 2012*.

Smith, J., Bruce, A. S., Glusman, M., Thelen, J., Lynch, S., & Bruce, J. M. (2018). Determining reliable change on the modified fatigue impact scale (5-item version). *Multiple Sclerosis and Related Disorders, 20*, 22-24.

Smith, J. A., Flowers, P., & Larkin, M. (2009). *Interpretative phenomenological analysis: Theory, method and research*. Sage.

Smith, J. D. (2012). Single-case experimental designs: A systematic review of published research and current standards. *Psychological Methods, 17*(4), 510-550. https://doi.org/10.1037/a0029312

Smith, K. J., & McDonald, W. I. (1999). The pathophysiology of multiple sclerosis: The mechanisms underlying the production of symptoms and the natural history of the disease. *Philosophical Transactions of the Royal Society B: Biological Sciences, 354*(1390), 1649-1673. https://doi.org/10.1098/rstb.1999.0510

Srivastava, A., & Thomson, S. B. (2009). Framework analysis: A qualitative methodology for applied policy research. *Journal of Administration & Governance, 4*(2), 72-79.

Starkstein, S. E., & Mizrahi, R. (2006). Depression in Alzheimer's disease. *Expert Review of Neurotherapeutics, 6*(6), 887-895.

Stout, R. (2003). Behaviourism. *Think, 2*(5), 37-44.

Strober, L. B., Rao, S. M., Lee, J. C., Fischer, E., & Rudick, R. (2014). Cognitive impairment in multiple sclerosis: An 18 year follow-up study. *Multiple Sclerosis and Related Disorders, 3*(4), 473-481. https://doi.org/10.1016/j.msard.2014.03.004

Swoboda, C., Kratochwill, T., & Levin, J. (2010). Conservative dual-criterion method for single-case research: A guide for visual analysis of AB, ABAB, and multiple-baseline designs. *Wisconsin Center for Education Research Working Paper No, 13*, 495-512.

Tambling, R. B. (2012). A literature review of therapeutic expectancy effects. *Contemporary Family Therapy, 34*(3), 402-415.

Task Force on Promotion and Dissemination of Psychological Procedures. (1995). Training in and dissemination of empirically validated psychological treatments. *The Clinical Psychologist, 48*, 3−23.

Thielscher, C., Thielscher, S., & Kostev, K. (2013). The risk of developing depression when suffering from neurological diseases. *German Medical Science, 11*, Doc02. https://doi.org/https://doi.org/10.3205/000170

Thomas, P. W., Thomas, S., Hillier, C., Galvin, K., & Baker, R. (2006). Psychological interventions for multiple sclerosis. *The Cochrane Database of Systematic Reviews*(1), 1-54. https://doi.org/10.1002/14651858.CD004431.pub2

Thompson, R., Isaac, C. L., Rowse, G., Tooth, C. L., & Reuber, M. (2009). What is it like to receive a diagnosis of nonepileptic seizures? *Epilepsy & Behavior, 14*(3), 508-515. https://doi.org/10.1016/j.yebeh.2008.12.014

Tiemens, B. G., Ormel, J., Jenner, J. A., Van der Meer, K., Van Os, T. W. D. P., Van den Brink, R. H. S., Smit, A., & Van den Brink, W. (1999). Training primary-care physicians to recognize, diagnose and manage depression: does it improve patient outcomes? *Psychological Medicine, 29*(4), 833-847. http://library.lincoln.ac.uk/items/eds/edsbl/RN064978457

Tomm, K. (1987a). Interventive interviewing: Part I. Strategizing as a fourth guideline for the therapist. *Family Process, 26*(1), 3-13. https://doi.org/10.1111/j.1545-5300.1987.00003.x

Tomm, K. (1987b). Interventive interviewing: Part II. Reflexive questioning as a means to enable self-healing. *Family Process, 26*(2), 167-183.

Tomm, K. (1988). Interventive Interviewing: Part III. Intending to ask Llneal, circular, strategic, or reflexive questions? *Family Process, 27*(1), 1-15. https://doi.org/10.1111/j.1545-5300.1988.00001.x

Trivedi, M. H., & Kurian, B. T. (2007). Managing depressive disorders in patients with epilepsy. *Psychiatry (Edgmont), 4*(1), 26.

Trompetter, H. R., Ten Klooster, P. M., Schreurs, K. M., Fledderus, M., Westerhof, G. J., & Bohlmeijer, E. T. (2013). Measuring values and committed action with the Engaged Living Scale (ELS): Psychometric evaluation in a nonclinical sample and a chronic pain sample. *Psychological Assessment, 25*(4), 1235-1246.

Van de Ven, A. H., & Huber, G. P. (1990). Longitudinal field research methods for studying processes of organizational change. *Organization Science, 1*(3), 213-219.

van Straten, A., Geraedts, A., Verdonck-de Leeuw, I., Andersson, G., & Cuijpers, P. (2010). Psychological treatment of depressive symptoms in patients with medical disorders: A meta-analysis. *Journal of Psychosomatic Research, 69*(1), 23-32. https://doi.org/10.1016/j.jpsychores.2010.01.019

Veale, D. (2008). Behavioural activation for depression. *Advances in Psychiatric Treatment, 14*(1), 29-36.

Veazey, C., Ozlem Erden Aki, S., Cook, K. F., Lai, E. C., & Kunik, M. E. (2005). Prevalence and treatment of depression in Parkinson's disease. *The Journal of Neuropsychiatry and Clinical Neurosciences, 17*(3), 310-323.

Vetere, A., & Dallos, R. (2003). *Working systemically with families: Formulation, intervention and evaluation*. Karnac.

Vickrey, B. G., Hays, R. D., Harooni, R., Myers, L. W., & Ellison, G. W. (1995). A health-related quality of life measure for multiple sclerosis. *Quality of Life Research, 4*(3), 187-206.

Wampold, B. E., & Imel, Z. E. (2015). *The great psychotherapy debate: The evidence for what makes psychotherapy work*. Routledge.

Ware, J. J., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233. https://doi.org/10.1097/00005650-199603000-00003

Watson, J. B. (1913). Psychology as the behaviorist views it. *Psychological Review, 20*(2), 158.

Webb, E. J., Campbell, D. T., Schwartz, R. D., & Sechrest, L. (1966). *Unobtrusive Measures: Non-reactive Research in the Social Sciences*. Rand McNally.

Wilkinson, H. R., & das Nair, R. (2013). The psychological impact of the unpredictability of multiple sclerosis: A qualitative literature meta-synthesis. *British Journal of Neuroscience Nursing, 9*(4), 172-178. https://doi.org/10.12968/bjnn.2013.9.4.172

Wolery, M., Busick, M., Reichow, B., & Barton, E. E. (2010). Comparison of overlap methods for quantitatively synthesizing single-subject data. *The Journal of Special Education, 44*(1), 18-28. https://doi.org/doi:10.1177/0022466908328009

World Health Organization. (2006). *Neurological disorders: public health challenges*. World Health Organization.

World Health Organization. (2016). *What are neurological disorders?* Retrieved 20th July from http://www.who.int/features/qa/55/en/

Zeiss, A. M., Lewinsohn, P. M., & Munoz, R. F. (1979). Nonspecific improvement effects in depression using interpersonal skills training, pleasant activity schedules, or cognitive training. *Journal of Consulting and Clinical Psychology, 47*(3), 427-439. https://doi.org/10.1037//0022-006x.47.3.427

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica, 67*(6), 361-370.

Appendices

Appendix A

Cover letter and contact details as required by the journal

30th March 2020

Dawn M. Ehde, PhD

Editor, *Rehabilitation Psychology*

University of Washington

Dear Dr Ehde,

I am enclosing an empirical article submission to the *Rehabilitation Psychology* entitled, "Behavioural activation for low mood in Multiple Sclerosis: Single-case experimental design." The manuscript is 6335 words and includes three tables and three figures.

I wish for the manuscript to be given a masked review. My co-authors and I confirm that the enclosed complies with the APA ethical standards. Ethical approval was sought and provided by East Midlands – Nottingham 2 ethics committee (ref: 19/EM/0013). Additionally, my co-authors and I confirm that we have no conflicts of interest. This work was part funded by Health Education East Midlands, who had no input to the design or undertaking of the work. My co-authors and I confirm that the manuscript and data have not been previously published and that they are not presently under consideration for publication elsewhere. Professor Roshan das Nair will be serving as the corresponding author for this manuscript. All authors listed in the byline have agreed to the byline order and to the submission of the manuscript in this form. All authors were involved in the design, development, and/or undertaking of the work. I understand that, if accepted for publication, a certification of authorship form will be required that all co-authors will sign.

Listed below is the contact details for all authors, byline, and author note for final production (as instructed in the manuscript preparation guidance).

Sincerely,

Lloyd Oates

Contact details

Lloyd L. Oates, Trent Doctorate in Clinical Psychology, University of Lincoln and Lincolnshire Partnership NHS Foundation Trust, Lincoln, UK. Doctorate in Clinical Psychology, School of Psychology, College of Social Science, University of Lincoln, Sarah Swift Building First Floor, Brayford Pool, Lincoln, LN6 7TS, UK. Email: 16662517@students.lincoln.ac.uk Telephone: +44 (0)1522 886029

Nima Moghaddam, Trent Doctorate in Clinical Psychology, School of Psychology, College of Social Science, University of Lincoln, Sarah Swift Building First Floor, Brayford Pool, Lincoln, LN6 7TS, UK. Email: NMoghaddam@lincoln.ac.uk Telephone: +44 (0)1522 886029

Christopher Meek, Trent Doctorate in Clinical Psychology, University of Lincoln. Doctorate in Clinical Psychology, School of Psychology, College of Social Science, University of Lincoln, Sarah Swift Building First Floor, Brayford Pool, Lincoln, LN6 7TS, UK. Email: msxcm13@nottingham.ac.uk, Telephone: +44 (0)1522 886029

Nikos Evangelou, University of Nottingham and Nottingham University Hospitals NHS Trust. Division of Neurosciences, University of Nottingham, Nottingham, UK. Email: Nikos.Evangelou@nottingham.ac.uk, Telephone: +44 (0)1159709735

Roshan das Nair, Professor of Clinical Psychology & Neuropsychology, B19, Institute of Mental Health, Jubilee Campus, University of Nottingham, Nottingham, NG7 2TU, UK. Email: Roshan.Dasnair@nottingham.ac.uk Telephone: +44 (0) 115 74 84240

Appendix B

Ethics approval letter

NHS
Health Research Authority

East Midlands - Nottingham 2 Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

04 March 2019

Dr Nima Moghaddam
Trent DClinPsy Programme
University of Lincoln
Brayford Pool, Lincoln
LN6 7TS

Dear Dr Moghaddam

Study title:	**Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)**
REC reference:	**19/EM/0013**
Protocol number:	**181001**
IRAS project ID:	**254182**

Thank you for your letter of 25 February 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Dr John Shaw.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [BALMS Study advert]	2	06 February 2019
Covering letter on headed paper [BALMS Cover Letter 19/EM/0013]	1	15 February 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	1	
GP/consultant information sheets or letters [BALMS GP Information sheet]	2	06 February 2019
Interview schedules or topic guides for participants [BALMS Interview schedule]	1	19 March 2018
IRAS Application Form [IRAS_Form_17122018]		17 December 2018
Laboratory Manual [The Revised Treatment Manual for the Brief Behavioral Activation Treatment for Depression (BATD-R)]	1	08 January 2019
Letter from sponsor [BALMS Sponsor letter]	1	28 November 2018
Other		
Other [BALMS Participant materials - behavioural activation]	1	08 January 2019
Other [BALMS Participant materials - depression]	1	08 January 2019
Other [BALMS Participant materials - identifying values]	1	19 March 2018
Participant consent form [BALMS Consent form]	2	06 February 2019
Participant information sheet (PIS) [BALMS Participant Information Sheet]	2	06 February 2019
Research protocol or project proposal [Behavioural Activation for Low Mood in Multiple Sclerosis protocol]	1	25 June 2018
Sample diary card/patient card [BALMS activity diary]	1	25 June 2018
Summary CV for Chief Investigator (CI) [Summary CV Nima Moghaddam]	1	25 June 2018
Summary CV for student [Summary CV Lloyd Oates]	1	13 September 2018

Summary CV for supervisor (student research) [Summary CV Roshan das Nair]	1	28 February 2018
Summary CV for supervisor (student research) [Summary CV Nima Moghaddam]	1	28 February 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [BALMS Study flow chart]	1	25 June 2018
Validated questionnaire [Health status questionnaire]		
Validated questionnaire [Behavioural activation and depression scale - short form]		
Validated questionnaire [Hospital Anxiety and Depression Scale]		
Validated questionnaire [Patient health status questionnaire 2]		
Validated questionnaire [Engaged Living Scale]		
Validated questionnaire [Modified fatigue impact scale - Page 23]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

19/EM/0013	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Ms Bernadette Roberts
Chair

Email: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mrs Sam Lewis*
Mrs Charlene Otieno-Hall, Nottingham University Hospitals NHS Trust

Appendix C

HRA approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Nima Moghaddam
Trent DClinPsy Programme
University of Lincoln
Brayford Pool, Lincoln
LN6 7TS

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

04 March 2019

Dear Dr. Moghaddam,

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)**
IRAS project ID:	**254182**
Protocol number:	**181001**
REC reference:	**19/EM/0013**
Sponsor	**University of Lincoln**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Mrs Sam Lewis
Tel: 01522 83 5490
Email: sponsor@lincoln.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **254182**. Please quote this on all correspondence.

Yours sincerely

IRAS project ID	254182

Laura Greenfield
Assessor

Email: hra.approval@nhs.net

Copy to: *Mrs Sam Lewis [Sponsor Contact on behalf of University of Lincoln]*
Mrs Charlene Otieno-Hall [Lead NHS R&D Office Contact on behalf of Nottingham University Hospitals NHS Trust]

Appendix D

Letter of access

Nottingham University Hospitals NHS
NHS Trust

Research & Innovation
Nottingham Integrated Clinical Research Centre
C Floor, South Block
QMC Campus
Derby Road
Nottingham
NG7 2UH

Tel: 0115 970 9049

www.nuhrise.org

RSCH936

15/07/2019

Lloyd Oates
Trent Doctorate in Clinical Psychology
Sarah Swift Building
University of Lincoln
Brayford Pool
Lincoln
LN6 7TS

Dear Lloyd Oates

Letter of access for research

Study Title:	Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)
Principal Investigator at NUH:	Nikos Evangelou
IRAS ID: 254182	**R&D Ref:** 19CP001
Sponsor:	The University of Lincoln

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is responsible for ensuring such checks as are necessary have been carried out. This letter confirms your right of access to conduct research through **Nottingham University Hospitals** for the purpose and on the terms and conditions set out below. This right of access commences from **the date of confirmation of capacity** and ends on **03/02/2020** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to **Nottingham University Hospitals** premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **Nottingham University Hospitals,** you will remain accountable to your employer **Lincolnshire Partnership NHS Foundation Trust** but you are required to follow the reasonable instructions of your nominated manager **Nikos Evangelou** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate

fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **Nottingham University Hospitals** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **Nottingham University Hospitals** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **Nottingham University Hospitals** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Nottingham University Hospitals will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

K. Asher.

Karen Asher
Divisional Research & Innovation Manager

cc: HR department of the substantive employer

NHS to NHS letter of access: proforma confirmation of pre-engagement checks
Version 1

For NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, and who need an NHS to NHS letter of access from an NHS organisation hosting their research

CONFIRMATION OF PRE-ENGAGEMENT CHECKS

To: R&D Office

Research and Innovation
QMC
Derby Road
Nottingham
NG7 2UH

Re: **Researcher's name: Lloyd Oates**

Job title: Trainee Clinical Psychologist

Contract end-date: September 2020

Workplace and postal address: University of Lincoln.

Electronic Staff Record number: 26898726.

As the representative of the NHS employer[1] of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, commensurate with her/his job description and proposed research role in your NHS organisation, and in line with NHS employment checks standards

Name of employer's representative: Samantha Brockington

Job Title: Recruitment Team Leader

12-7-19

Workplace address: Unit 9, The Point, Sleaford, Lincolnshire, NG34 8GG

Tel: 01529 222282
Email: Samantha.brockington@lpft.nhs.uk

[1] For clinical academics, this would be a representative from their HEI employer

Appendix E

Participant consent form

UNIVERSITY OF LINCOLN

CONSENT FORM

Title of Study: Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)
IRAS Project ID: 254182
Name of Researcher: Lloyd Oates
Participant ID Number: _____

Please initial box

1. I confirm that I have read the information sheet dated 06/02/19 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Lincoln, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, I understand that my personal details will be kept confidential. ☐

4. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers. ☐

5. I agree to my General Practitioner being informed of my participation in the study. ☐

6. I would like to receive a summary of the results of the study. YES ☐ NO ☐

7. I agree to be emailed once a year about remaining on a contact list for involvement in potential future studies. YES ☐ NO ☐

8. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix F

Study advert

Do you have Secondary Progressive MS?

Have you stopped doing activities you really enjoy?

Have you noticed your mood has become lower?

If so, a new study may be of benefit to you.

We would like you to take part in a research project that involves identifying activities that link closely to the things that matter to you most to improve mood. You would take part in one-to-one sessions, that are structured around Behavioural Activation. Behavioural activation involves finding activities that you may enjoy or get a sense of achievement from and gradually introducing the activities into your week.

During the study a researcher will support you to identify new activities and help you consider how to restart old hobbies. The sessions will be both face-to-face and through your computer, using a video calling programme. You will meet the researcher on five occasions and take part in a brief interview after the final session.

If you would like to know more about the research, then please contact me to discuss further and receive a more detailed information pack: 16662517@students.lincoln.ac.uk

Making contact does not commit you to taking part. You will be able to ask any questions to learn more about the study, to help you make an informed choice.

This study is being undertaken as part of the qualification for a Doctorate in Clinical Psychology and is supervised by:

Professor Roshan das Nair: Roshan.dasnair@nottingham.ac.uk
Dr. Nima Moghaddam: NMoghaddam@lincoln.ac.uk
Dr. Nikolaos Evangelou: Nikos.Evangelou@nottingham.ac.uk

Appendix G

Participant information sheet

Participant Information Sheet
(Version 2: 06/02/2019)
IRAS ID: 254182

Title of Study: Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)
Name of Researcher and Supervisors: Lloyd Oates (Researcher), Professor Roshan das Nair (Supervisor), Dr. Nima Moghaddam (Supervisor), and Dr. Nikolaos Evangelou (Supervisor)

We'd like to invite you to take part in our research study. The study is being undertaken as part of the qualification for a Doctorate in Clinical Psychology. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide if you would like to take part and answer any questions you may have. We'd suggest this should take about 15 minutes. Please feel free to talk to others about the study if you wish.

What is the purpose of the study?
Living with Multiple Sclerosis can present many different challenges for people. Uncertainty and changing physical abilities may mean that people take part less in activities they usually enjoy. People diagnosed with secondary progressive Multiple Sclerosis can find it difficult to take part in hobbies and interests and it can be hard to find new activities to replace them. People can experience low mood and fatigue as a result.

Waiting lists for regular NHS psychological therapies can be long and often are not specifically tailored for people with secondary progressive Multiple Sclerosis. So, we are investigating a psychological therapy that has been adapted for people with secondary progressive Multiple Sclerosis, across Nottinghamshire. We would like to investigate if the therapy helps reduce depression. We would also like to understand people’s experiences of the therapy.

Why have I been invited?

You are being invited to take part because you have a diagnosis of secondary progressive Multiple Sclerosis and have expressed that you have been experiencing low mood. We are inviting ten participants like you to take part.

Do I have to take part?
It is up to you to decide whether to take part. If you decide to take part you will be given this information sheet to keep, a short questionnaire to complete, and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you have been informed of the study by the Multiple Sclerosis care team or have seen an advertisement for the study in the MS Society Nottingham Branch, you have already likely had a discussion with the researcher and been sent this information sheet.

Once you have read the information sheet and had any questions answered by the researcher, you will be asked to complete a short screening questionnaire (Hospital Anxiety and Depression Scale) and a consent form. The questionnaire will then be scored. Depending on your score, you will be asked if you would like to continue in the study.

If you would like to continue you will then be asked to complete an online questionnaire. Following this you will be sent a text message every two days, to answer eleven brief questions (which form part of two questionnaires - the Patient Health Questionnaire 2 and the Behavioural Activation for Depression Scale – Short form). You will receive the text messages for a minimum of two weeks and up to four weeks. After the fourth week it is possible that taking part may come to an end.

If you are asked to continue, the researcher will contact you to arrange a visit to your home. During this visit the researcher will ask you questions about your interests, hobbies, and the difficulties you experience because of your Multiple Sclerosis. You will then be asked to complete a pack of questionnaires online and the following appointment time will be arranged.

The next four sessions will take place fortnightly using an internet video calling system (such as Skype). During these sessions the researcher will support you to identify activities you would like to complete and to consider any difficulties you may have with this. At

the end of the session the researcher will set tasks for the week, such as maintaining a diary of your activities. Each week during the sessions you will be asked (by text reminder) to answer the questionnaires online.

After the fourth session you will be contacted to discuss the activities you completed over the last fortnight and asked to complete the questionnaires.

Each session will be audio recorded. A random selection of the recordings will be listened to by an independent researcher. The independent researcher will check that the content of the sessions adhered to the manual being used to structure the support. Following the review at the end of your involvement in the study, all audio recordings will be erased. The recordings may include the use of your first name, however, any further identifiable information will be removed, prior to review, using audio editing software. The audio recordings will not be transcribed.

After the last session you will be contacted by a Trainee Clinical Psychologist, who is not involved in the study design, to take part in a 30-minute interview over the phone. During the interview you will be asked about your opinion of the sessions. Two months after this you will be invited to complete the questionnaires one final time.

If at any time you no longer wish to take part, you can contact the researcher. You do not need to provide a reason, but, the researcher will ask if you would like to take part in the interview. We will ask this as it may help us to understand your experience of the therapy sessions.

Expenses and payments
To thank you for your support we would like to give you a £20 amazon voucher. The voucher will be sent to you after the interview.

What are the possible disadvantages and risks of taking part?
You need to be aware that you will be asked to complete questionnaires every week. It is not expected that the questionnaires will take longer than 15-minutes. During the first 2-4 weeks, you will be asked to answer questions every two days. These questions are not expected to take longer than five minutes.

What are the possible benefits of taking part?
Whilst it is currently unknown what, if any, direct benefits may occur during the study, you will contribute to the ongoing collection of knowledge of working psychologically with people with Multiple Sclerosis. The hope is to identify potential future benefits.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting ethics@lincoln.ac.uk.

If you feel that we have let you down in relation to your information rights then please contact the Information Compliance team by email on compliance@lincoln.ac.uk or by post at Information Compliance, Secretariat, University of Lincoln, Brayford Pool, Lincoln, LN6 7TS.

You can also make complaints directly to the Information Commissioner's Office (ICO). The ICO is the independent authority upholding information rights for the UK. Their website is ico.org.uk and their telephone helpline number is 0303 123 1113.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Lincoln who are organising this research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Your personal details will be kept in a separate location to your research details, as guided by GDPR (previously Data Protection Act). Any information about you which leaves the university will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

The research data which will have no identifiable information will be kept for five years after the end of the study. All research data will be kept securely for five years in accordance with university policy. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the sessions or interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons, but you will be kept informed of this process.

The researchers will collect information from you for this research study in accordance with our instructions.

Nottinghamshire University Hospitals NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Lincoln and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Nottinghamshire University Hospitals NHS Foundation Trust will pass these details to the University of Lincoln along with the information collected from you and your medical records. The only people in the University of Lincoln who will have access to information that identifies you will be people who need to contact you to enrol you into the study, complete the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
Nottinghamshire University Hospitals NHS Foundation Trust will keep identifiable information about you from this study for five years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Privacy notice
The University of Lincoln is the sponsor for this study based in the United Kingdom. We will be using information from you in order to

undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Lincoln will keep identifiable information about you for up to 12 months after the study, so we can send you a summary.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. We will ask if you give permission for us to contact you about *possible follow-up studies*. If you give permission, you will be emailed once a year to ask if you would like to remain on the contact list.

You can find out more about how we use your information at https://ethics.sites.lincoln.ac.uk/research-privacy-notice/

What will happen if I don't want to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time without giving any reason and without your legal rights being affected. If you withdraw once analysis has begun, then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of the research will be written up as part of the researcher's major thesis for the Doctorate in Clinical Psychology. A further paper will be written for publication in a relevant journal and a report will be prepared for the MS Society. The results are likely to be published mid-2020, if you have requested a copy this will be sent you either by email or post (whichever you prefer). You will not be identifiable in any publications.

Who is organising and funding the research?
This research is being organised and funded by the University of Lincoln.

Who has reviewed the study?
All research conducted by the University of Lincoln is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the University of Lincoln Research Ethics Committee and East Midlands - Nottingham 2 Research Ethics Committee.

Further information and contact details

Chief Investigator:
Dr. Nima Moghaddam: NMoghaddam@lincoln.ac.uk

Primary Investigator:
Lloyd Oates: 16662517@students.lincoln.ac.uk

Supervised By:
Professor Roshan das Nair: Roshan.dasnair@nottingham.ac.uk
Dr. Nima Moghaddam: NMoghaddam@lincoln.ac.uk
Dr. Nikolaos Evangelou: Nikos.Evangelou@nottingham.ac.uk

Postal Contact Details:
Doctorate in Clinical Psychology
School of Psychology
College of Social Science
University of Lincoln
1st Floor, Sarah Swift Building
Brayford Pool
Lincoln
LN6 7AY

Appendix H

Hospital Anxiety and Depression Scale and permission

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

The University of Nottingham has permission for students to use the measure for research purposes.

Appendix I

MS Society managing emotions

https://www.mssociety.org.uk/ms-resources/ms-and-your-emotions-understanding-and-dealing-your-feelings

MS

Multiple Sclerosis Society

MS and your Emotions:

Understanding and dealing with your feelings

Appendix J

GP information sheet

GP Information Sheet
(Version 2: 06/02/2019)
IRAS ID: 254182

Title of Study: Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)
Researcher: Lloyd Oates
Supervisors: Professor Roshan das Nair (Clinical Psychologist), Dr. Nima Moghaddam (Clinical Psychologist), and Dr. Nikolaos Evangelou (Neurologist)

GP Address

Dear Dr X,

Re: client details: Name, D/O/B, address

Your patient, named above, has given their consent to take part in the behavioural activation for low mood in Multiple Sclerosis study. This is a multiple single-case experimental design study, which aims to establish whether behavioural activation (a psychotherapy technique) reduces depression in people with secondary progressive Multiple Sclerosis.

Name has indicated that they had been feeling low in mood and had been struggling to engage in activities that they previously enjoyed. Name was screened for study inclusion using the Hospital Anxiety and Depression Scale and scored X/X on the depression subscale and X/X on the anxiety subscale.

During the study name will receive a single face-to-face session followed by up to four internet-based video sessions, delivered by a Trainee Clinical Psychologist. During the study name will complete outcome measures relating to low mood, fatigue, quality of life, and engagement in the intervention. Following the intervention sessions name may be asked to take part in a 30-minute phone interview with a Trainee Clinical Psychologist independent of the study design to explore their experience of the study. Name will be asked two-months after the interview if they would like to complete the outcome measures one final time.

A copy of the Participant Information Sheet is included for your information. If you have any questions or would like any further information about the study please contact me.

Yours Sincerely

Lloyd Oates
Trainee Clinical Psychologist

This study is being undertaken as part of the qualification for a Doctorate in Clinical Psychology by Lloyd Oates.

Chief Investigator:
Dr. Nima Moghaddam: NMoghaddam@lincoln.ac.uk
Phone: 01522 886029 (University of Lincoln - Doctorate in Clinical Psychology administration team)

Supervised By:
Professor Roshan das Nair: Roshan.dasnair@nottingham.ac.uk
Dr. Nima Moghaddam: NMoghaddam@lincoln.ac.uk
Dr. Nikolaos Evangelou: Nikos.Evangelou@nottingham.ac.uk

Appendix K

Demographic and clinical information form

Item	
PS ID	
Age	
Gender	
Relationship status	
Care status	
Ethnicity	
Education level	
Employment status	
Diagnosis	
Disease duration and progression history (When were you diagnosed? When were you diagnosed with SPMS?)	

Appendix L

Patient Health Questionnaire-2 (PHQ-2) and permission

The Patient Health Questionnaire-2 (PHQ-2)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

Appendix M

Engaged Living Scale (ELS) and permission

Engaged Living Scale*

The following questions concern 'value based living.' Values are the choices that we make about how we want to live our lives. This means that you determine what you believe to be important in your life, what makes it all worthwhile and what motivates you. The question that you ask yourself here is what do I want from life? What do I consider important and what sort of person do I want to be? This questionnaire is about learning to identify these values and to live according to them.

1. I have values that give my life more meaning. (VL)
2. I know what motivates me in life. (*VL*)
3. I believe that I've found important values to live according to. (*VL*)
4. I know exactly what I want to do with my life. (*VL*)
5. I make choices based on my values, even if it is stressful. (*VL*)
6. I know how I want to live my life. (*VL*)
7. I know what I want to do with my life. (*VL*)
8. I believe that my values are really reflected in my behaviour. (*VL*)
9. I believe that how I behave fits in with my personal wants and desires. (*VL*)
10. My emotions don't hold me back from doing what's important to me. (*VL*)
11. I live the way I always intended to live. (*LF*)
12. I am satisfied with how I live my life. (*LF*)
13. Nothing can stop me from doing something that's important to me. (*LF*)
14. I believe that I am living life to the full right now. (*LF*)
15. I make time for the things that I consider important. (*LF*)
16. I feel that I am living a full life. (*LF*)

*This questionnaire was translated from Dutch to English and translated back to Dutch by independent native speakers to ensure reliable translation. All items are scored on a 5-point Likert scale, ranging from 'completely disagree' to 'completely agree.' No reversed scoring of items is necessary. Sum scores can be calculated for each subscale and for the total scale.

Received November 28, 2012
Revision received May 24, 2013
Accepted June 3, 2013 ■

H.R. Trompetter <H.R.Trompetter@uvt.nl>
Thu 06/09/2018 10:17
Lloyd Oates (16662517)
Trompetter H - Dissertation - ACT with Pain.pdf
5 MB

Dear Lloyd,

Thank you for your interest in the Engaged Living Scale. I happily grant you permission to use the scale in your research. You can find the items in the appendix of the published paper – items were thoroughly (back-)translated from Dutch to English (see page 92 of my attached dissertation).

I wish you all the best with your thesis.

Kind regards,
Hester Trompetter

From: Lloyd Oates (16662517) [mailto:16662517@students.lincoln.ac.uk]
Sent: dinsdag 4 september 2018 4:11
To: h.r.trompetter@tilburguniversity.edu
Subject: Engaged living scale permissions

Dear Dr Trompetter,

I am a Doctorate in Clinical Psychology student at the University of Lincoln and the University of Nottingham. For my upcoming thesis of Behavioural Activation for low mood in people with multiple sclerosis I would like to use the Engaged Living Scale as

an outcome measure. I hope I am correct in emailing you for permissions to use the measure. If I need to contact someone else in regard to permissions, I would be grateful if you could let me know how to go about this.

Best wishes

Lloyd Oates
Trainee Clinical Psychologist

Appendix N

Behavioural Activation for Depression Scale – Short Form (BADS-SF) and permission

Please read each statement carefully and then circle the number which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0 = Not at all 1 2 = A little 3 4 = A lot 5 6 = Completely	0	1	2	3	4	5	6	AC	AV	T
1. There were certain things I needed to do that I didn't do.	○	○	○	○	○	○	○	_		R
2. I am content with the amount and types of things I did.	○	○	○	○	○	○	○	_		_
3. I engaged in many different activities.	○	○	○	○	○	○	○	_		_
4. I made good decisions about what type of activities and/or situations I put myself in.	○	○	○	○	○	○	○	_		_
5. I was an active person and accomplished the goals I set out to do.	○	○	○	○	○	○	○	_		_
6. Most of what I did was to escape from or avoid something unpleasant.	○	○	○	○	○	○	○		_	R
7. I spent a long time thinking over and over about my problems.	○	○	○	○	○	○	○		_	R
8. I engaged in activities that would distract me from feeling bad.	○	○	○	○	○	○	○		_	R
9. I did things that were enjoyable.	○	○	○	○	○	○	○	_		_
								___	___	___

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Depression
Treatment Specialty Clinic
Department of Psychology
PO Box 413, Milwaukee, WI 53201
Pearse Hall 179 (414) 229-5521

October 2, 2012

To whom it may concern,

Thank you for your interest in the Behavioral Activation for Depression Scale – Short Form (BADS-SF).

The short form is 9 items, 8 of which are from the original BADS (with a few minor changes) and one new item. The range of scores is 0 to 54, with high scores representing higher activation.

Factor analyses have identified 2 subscales of the short form, which are *Activation* (AC) and *Avoidance* (AV). Because of the small number of items in the subscales, we do not recommend that they be calculated and used separately from the total scale, but they do give a sense for the composition of the total scale and what a total scale score means.

Even though we do not recommend it, if you do want to score the subscales, sum the items for each subscale to generate subscale scores (indicated by hash marks on the columns on the right). None of the items should be reverse scored for the subscales.

For the total score (T), follow the markings on the column furthest to the right. High scores on the total scale indicate greater levels of activation. Items with an "R" in the scoring template should be reverse scored for the total score only. This means that an item on the Avoidance subscale will get reverse-scored when computing the total score of the BADS-SF, but it will not get reverse-scored when computing the Avoidance subscale score (which we don't recommend you use anyway). This procedure makes the subscale and total scale scores consistent with the title of the subscale or scale. In other words, a high score on the total scale means more activation, while a high score on the Avoidance subscale means more avoidance.

The short form has several advantages over the original and you may want to consider using it. Specifically, the BADS-SF is more focused directly on the types of activation and avoidance targets in BA treatments and does not contain items on impairment, which may be conceptualized as *resulting* from changes in activation and avoidance rather than part of the processes taking place in BA treatments. The BADS-SF is also shorter (9 items), has good construct validity demonstrated by significant correlations with measures of depression (CES-D) as well as a variety of other measures (i.e., AAQ, ATQ, BAI, CBAS, EROS, PES), and predictive validity over a one-week time period predicting engagement in highly rewarding or pleasant activities or unrewarding and unpleasant activities.

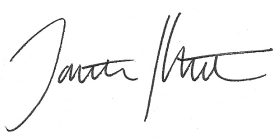
The proper reference for the short form is:

Manos, R. C., Kanter, J. W., & Luo, W. (2011). The Behavioral Activation for Depression Scale-Short Form: Development and validation. *Behavior Therapy*, 42, 726-739.
Please contact Dr. Jonathan Kanter by email at jkanter@uwm.edu or by phone at 414-229-3834 if you have any comments or questions about either the BADS or the BADS-SF.

In accepting this scale from us, you are giving us permission to contact you at a later date so we may inquire about its use and any data you may have on it. There is no obligation to share data with us but we do hope for a collegial response to later requests for updates or possible collaborations on publications regarding the continued development and evaluation of these measures.

Thank you and good luck with your work.

Sincerely,



Jonathan Kanter, Ph.D.
Director, Depression Treatment Specialty Clinic
Coordinator, UWM Psychology Clinic
Associate Professor, Clinical Psychology
Research Scientist, Center for Addiction and Behavioral Health Research
University of Wisconsin-Milwaukee

Appendix O

Modified Fatigue Impact Scale – Short Form (MFIS-SF) and permission

Patient's Name: _____ **Date:** _____/____/____
month day year

ID#: _____ **Test#:** **1 2 3 4**

MODIFIED FATIGUE IMPACT SCALE - 5-ITEM VERSION (MFIS-5)

Following is a list of statements that describe how fatigue may affect a person. Fatigue is a feeling of physical tiredness and lack of energy that many people experience from time to time. In medical conditions like MS, feelings of fatigue can occur more often and have a greater impact than usual. Please read each statement carefully, and then circle the one number that best indicates how often fatigue has affected you in this way during the past 4 weeks. (If you need help in marking your responses, tell the interviewer the number of the best response.) Please answer every question. If you are not sure which answer to select, please choose the one answer that comes closest to describing you. The interviewer can explain any words or phrases that you do not understand.

Because of my fatigue during the past 4 weeks....

		Never	Rarely	Sometimes	Often	Almost always
1.	**I have been less alert.**	**0**	**1**	**2**	**3**	**4**
2.	**I have been limited in my ability to do things away from home.**	**0**	**1**	**2**	**3**	**4**
3.	**I have had trouble maintaining physical effort for long periods.**	**0**	**1**	**2**	**3**	**4**
4.	**I have been less able to complete tasks that require physical effort.**	**0**	**1**	**2**	**3**	**4**

5. I have had trouble

concentrating.	**0**	**1**	**2**	**3**	**4**

What permission is there	1 National Unlimited Permission
Further Notes	National Multiple Sclerosis Society has confirmed that the tool is in the public domain, however please do not make any changes to the items on the form as this may impact on the validity of the tool, for more information see the manual.

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
Thank you for completing this survey!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

3. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the <u>past 4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

OPTUM™

NON-COMMERCIAL LICENSE AGREEMENT
Office of Grants and Scholarly Research (OGSR)

License Number: QM047364

Licensee Name: Lloyd Oates c/o University of Lincoln

Licensee Address: 9 Balkwell Avenue, North Shields, Tyne and Wear NE29 7JN GB

Approved Purpose: Behavioural Activation for Low mood in Multiple Sclerosis

Study Name: Thesis/Dissertation
Study Type: Non-commercial academic research and/or thesis – Unfunded Student
Data Collection Method: Interview Script and Paper

Therapeutic Area: Mental Health and Behavior
Indication: Depression

Royalty Fee: None, because this License is granted in support of the non-commercial Approved Purpose

A. Effective Date: This Non-Commercial License Agreement (the "Agreement") from the Office of Grants and Scholarly Research (OGSR) is made by and between OptumInsight Life Sciences, Inc. (f/k/a QualityMetric Incorporated) ("Optum"), 1301 Atwood Ave, Suite 311N, Johnston, RI 02919 and Licensee. This Agreement is entered into as of the date of last signature below and is effective for the Study Term set forth on Appendix B.

B. Appendices: Capitalized terms used in this Agreement shall have the meanings assigned to them in Appendix A and Appendix B. The appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

C. Grant of License: Subject to the terms of this Agreement, Optum grants to Licensee a non-exclusive, non-transferable, non-sublicensable worldwide license to use, solely for the Approved Purpose and during the Study Term, the Licensed Surveys, Software, SMS Scoring Solution, and all intellectual property rights related thereto ("Survey Materials"), in the authorized Data Collection Method, Modes of Administration, and Approved Languages indicated on Appendix B; and to administer the Licensed Surveys only up to the total number of Administrations (and to make up to such number of exact reproductions of the Licensed Surveys necessary to support such Administrations) in any combination of the specific Licensed Surveys and Approved Languages, Data Collection Method, and Modes of Administration.

EXECUTED by the duly authorized representatives as set forth below.

OptumInsight Life Sciences, Inc.	**Lloyd Oates**
Signature: DocuSigned by: Dr Michelle K White	Signature:
Name: Dr Michelle K White	Name: Lloyd Oates
Title: Vice President and Senior Scientist	Title: Mr
Date: 15-October 2018	Date: 11th October 2018

OPTUMINSIGHT NON-COMMERCIAL LICENSE TERMS AND CONDITIONS - APPENDIX A

Attached to and Incorporated into License No. QM047364

1. **No Commercial Use of Data - Licensee agrees to use the data resulting from Licensee's administration of the Survey Materials only for the Approved Purpose and related academic or scientific uses. Licensee agrees not to use such data for any other purpose or to provide such data to any commercial entity or to any entity for commercial purposes, including without limitation any university or university hospital.**

2. Copyright Protection. The Survey Materials are copyrighted works owned by Optum. Copyright protection means that Licensee cannot reproduce, copy, modify, or distribute the Survey Materials or any part of them without Optum's consent, even if the Survey Materials were not obtained from Optum. This Agreement constitutes Optum's consent for Licensee to use the Survey Materials only as specified in this Agreement.

3. Term and Termination – This Agreement shall be effective until the earlier to occur of (a) completion or termination of Services in connection with the Approved Purpose, or (b) expiration of the Study Term specified in Appendix B (if any), after which the licenses granted hereunder shall terminate and this Agreement shall terminate upon full payment therefore. Notwithstanding the foregoing, either party may terminate this Agreement at any time in the event of a material breach of this Agreement by the other party that is not cured within thirty (30) days following notice to the breaching party.

4. Administration by Students and Third Parties – Students of Licensee may use and administer the Licensed Surveys, subject to each such students' execution of OptumInsight's Acknowledgement by Students form, available by request. A third party service provider may administer the Licensed Surveys on behalf of Licensee subject to such third party's execution of Optum's Acknowledgement by Agent form; provided, that Licensee shall not be relieved of its obligations by use of such third party, and Licensee shall be responsible for any breach of this Agreement by such third party.

5. Trademark and Copyright Notices – Licensee agrees to reproduce the copyright and trademark notices included with the Survey Materials on all reproductions of the Survey Materials permitted hereunder, including electronic reproductions and representations. Licensee shall not alter the wording or order of the items or any other part of the Survey Materials. Licensee shall not create any derivative work from the Survey Materials.

6. Maintenance of Records – Licensee shall maintain accurate records containing information sufficient to verify Licensee's compliance with this Agreement, including, but not limited to, records of the number of reproductions of the Licensed Survey(s) made, the location of and/or confirmation of the destruction of such reproductions, and the number of administrations of the Licensed Survey(s) performed. Optum or a third party auditor of its choice reasonably acceptable to Licensee shall have the right, not more frequently than once in each calendar year and on thirty (30) days advance notice to Licensee, during usual business hours, to examine such records for the sole purpose of verifying Licensee's compliance with the terms of this Agreement.

7. Proprietary Rights –

   a. Licensee acknowledges that the Survey Materials shall be and remain at all times the property of Optum. Licensee shall have no right, title or interest in the Survey Materials except for the limited license described herein. Licensee shall not use, modify, reproduce, or transmit any of the Survey Materials except as expressly provided hereunder. If the Approved Purpose includes administration of the Licensed Surveys in physical form, Licensee is authorized to make exact reproductions of the Licensed Survey(s) sufficient to support such administrations. Licensee agrees that it shall not challenge or assist any other party in challenging the validity, ownership or enforceability of the Survey Materials.

   b. Licensee acknowledges and agrees that the Data Collection Method and Modes of Administration reflected in this Agreement are the only manner in which Licensee may administer the Licensed Surveys.

c. Licensee acknowledges and agrees that scoring of Licensed Survey(s) responses must be performed by Optum or by Licensee through use of an Optum scoring solution. Licensee shall not embed, input, insert, or transfer the Survey Materials, Optum's scoring algorithms (regardless of the source of the algorithms), or any part thereof, into Licensee's systems or applications absent purchase by Licensee of an Optum scoring solution.

d. Licensee acknowledges and agrees that any translations of the Licensed Surveys into any language must be performed by Optum, and Optum retains ownership of any and all translations.

e. Licensee acknowledges and agrees that the results, data and all information obtained through the utilization and administration of the Survey Materials are solely for the Licensee's own use and analysis, consistent with and as contemplated by the Approved Purpose, and may not be sold to, or otherwise, transferred for value (in any manner) to a third party.

f. Licensee may publish aggregated survey results in scientific and/or academic journals, papers, reports and presentations (the "Publications") related to the Approved Purpose. License may cite the Survey Materials and/or the reference materials provided Licensee includes the appropriate copyright and trademarks notices and Licensee does not indicate that Optum has endorsed the Publication in any manner. Licensee may not include a copy or any portion of the Survey Materials in any Publication including screenshots or excerpts of the Survey Materials.

8. Confidentiality; Injunctive Relief – Licensee acknowledges that the Survey Materials are valuable assets of Optum and that the value of the Survey Materials would be significantly impaired by the unauthorized distribution or use of them. Licensee shall ensure that the Survey Materials are not used for unauthorized purposes or by unauthorized persons, and shall promptly report any such unauthorized use to Optum. Licensee acknowledges that, in the event of any material breach of this paragraph by the Licensee, money damages would not be a sufficient remedy, and that Optum shall, to the extent permitted by applicable law, be entitled to equitable relief, including injunction. Such relief shall be in addition to all other remedies available at law or in equity.

9. Disclaimer of Warranty – Licensee acknowledges that complex and sophisticated products such as the Survey Materials are inherently subject to undiscovered defects. Optum cannot and does not represent or warrant to Licensee that the Survey Materials are free from such defects, that operation of the Survey Materials will be uninterrupted or error free, or that its results will be effective or suitable with respect to any particular application. SURVEY MATERIALS AND SERVICES HEREUNDER ARE PROVIDED AS-IS, AND OPTUM MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO SUCH SURVEY MATERIALS OR SERVICES, AND DISCLAIMS ALL WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR OTHERWISE.

10. Compliance. – Optum and Licensee agree that in performing their respective obligations under this Agreement, each shall conduct business in conformance with sound ethical standards of integrity and honesty and in compliance with all applicable laws, rules and regulations. Licensee represents and warrants that it has not and shall never engage in activities or use of the Survey Materials in a manner that is deceptive, scandalous, or involves moral turpitude, or in any other manner that could injure the high market acceptance, good name and reputation of Optum or the Survey Materials.

11. Limitation of Liability – In no event shall either party's total liability to the other party for direct damages arising hereunder exceed the amount of the Fees paid or owed by Licensee to Optum hereunder, except for damages from claims for breach of confidentiality, unauthorized use of Survey Materials or failure to indemnify for which there is no limit on direct damages. Further, in no event shall either party be liable to the other party for any special, punitive, incidental, indirect, or consequential damages, arising from any claimed breach of contract, or any other legal theory, even if such party has been advised of the possibility of such damages.

12. Intellectual Property Indemnification – Optum will defend, at its expense, any action brought against Licensee to the extent that it is based on a third party claim that a Licensed Survey infringes any patent, registered trademark, or copyright, provided that: (a) Licensee notifies Optum in writing within thirty (30) days of its becoming aware of any such claim; (b) Optum has sole control of the defense and all related settlement negotiations, provided that Optum shall not agree to any settlement that includes an admission of wrongdoing on the part of Licensee or requiring any action by

Licensee without Licensee's prior written consent; and (c) Licensee provides Optum with the information, authority, and any and all assistance reasonably required by Optum to provide the aforementioned defense. In the event of an action against Licensee alleging infringement of the intellectual property rights of a third party with respect to a Licensed Survey, or in the event Optum believes such a claim is likely, Optum shall be entitled, at its option but without obligation or additional cost to Licensee, to (i) appropriately modify such Licensed Survey so as not to infringe such third party intellectual property rights; provided, that such modifications or substitutions shall not materially affect the function of such Licensed Survey; (ii) obtain a license with respect to the applicable third party intellectual property rights; or (iii) if neither (i) nor (ii) is commercially practicable, terminate Licensee's license hereunder as to the effected Licensed Survey and refund the full license fee therefore. Optum shall have no liability hereunder if the alleged infringement is caused by use of other than the then-most-recent version of such Licensed Survey provided to Licensee by Optum, any combination of a Licensed Survey with non-Optum programs or data, where the Licensed Survey alone would not have given rise to the claim, or (iii) use of a Licensed Survey outside the scope of this Agreement. THIS SECTION STATES THE ENTIRE LIABILITY OF OPTUM AND LICENSEE'S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY ALLEGED INFRINGEMENT.

13. Scoring -

a. Licensee acknowledges and agrees that scoring of Licensed Survey responses must be performed by Optum or by Licensee through the use of an Optum scoring solution. Licensee shall not embed, input, or transfer the Survey Materials, Optum's scoring algorithms (regardless of the source of the algorithms), or any part thereof, into any systems or applications without an appropriate written agreement with Optum.

b. Scoring Software. Licensee may install and use one copy of the desktop scoring software provided by Optum to Licensee under this Agreement ("Software") on a single computer, and may not otherwise copy the Software. However, upon execution of an Acknowledgement by Agent form by a clinical research organization or other third party vendor acting on Licensee's behalf ("Agent"), Licensee shall have the right to transfer its copy of the Software (without retaining a copy) to the Agent for use solely on Licensee's behalf, provided that Licensee warrants to Optum that Agent shall abide by all terms and conditions of this Agreement and Licensee shall be responsible for any breach of this Agreement by such Agent. The Software may not be copied, shared or used concurrently on different computers. Licensee may not reverse engineer, decompile, or disassemble the Software, nor attempt in any other manner to obtain the source code. The Software and the algorithms it contains are proprietary information of Optum. Licensee shall not attempt to circumvent any function of the Software that limits its use to a certain number of administrations of the Licensed Surveys or to a certain time period. Licensee may not rent or lease the Software to any other person.

c. Optum Smart Measurement System ("SMS") Scoring Solution. The "SMS Scoring Solution" shall mean the algorithmic scoring engine that scores Licensed Survey responses collected on Optum's web-based survey administration interface. Licensee may not reverse engineer, decompile, or disassemble the SMS Scoring Solution, nor attempt in any other manner to obtain the source code for it. The SMS Scoring Solution and the algorithms it contains are proprietary information of Optum. Licensee shall not attempt to circumvent any function of the SMS Scoring Solution that limits its use to a certain number of administrations of the Licensed Surveys or to a certain time period. Licensee may not rent or lease the SMS Scoring Solution to any other person.

14. Form Review – If Appendix B permits Licensee to administer the Licensed Surveys on an electronic device, Licensee is required to submit screen shots or a link to the Licensed Surveys for each Approved Language to Optum. Optum shall perform an initial form review to determine whether the Licensed Surveys have been appropriately migrated to electronic format (the "Initial Review"). Optum will complete its Initial Review of the Licensed Surveys for each Approved Language within two (2) weeks from Optum's receipt of screen shots or website link from Licensee. Upon Optum's completion of the Initial Review, Optum will provide Licensee with a detailed list of revisions that will need to be made before Optum can approve the electronic format. Licensee is required to submit subsequent screen shots or a link to the Licensed Surveys for each Approved Language incorporating any changes required by Optum until Optum provides its final approval of the electronic format. Multiple rounds of review and revisions may be necessary prior to Optum being able to provide final approval of the electronic format. Licensee is solely responsible for the electronic creation of the Licensed Surveys. Nothing in this Agreement prohibits Optum from creating its own electronic forms of Licensed Survey administration. The Licensed Surveys cannot be used in electronic format except as allowed pursuant to the terms and conditions of this Agreement. Licensee acknowledges that there may be response differences due to effects from use of

electronic format compared to a static Data Collection Method and Mode of Administration such as paper/pencil. Licensee assumes any and all risk of differential effects resulting from the use of electronic format.

15. Miscellaneous

a. Neither party may use the other party's name in any press release, web site, promotional material or other form of publicity without the prior written approval of such party.

b. This Agreement constitutes the entire and exclusive agreement between the parties and supersedes all previous communications or agreements, either oral or written, with respect to the subject matter hereof. This Agreement may not be modified or amended except by an instrument in writing signed by both parties. The Appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

c. Any waiver of any breach or default under this Agreement must be in writing and shall not be deemed a waiver of any other or subsequent breach or waiver. Failure or delay by either party to enforce compliance with any term or condition of this Agreement shall not constitute a waiver of such term or condition.

d. If any provision in this Agreement is determined to be invalid or unenforceable, the remaining provisions shall not be affected thereby and shall be binding upon the parties hereto, as though the invalid or unenforceable provision were not contained herein.

e. In the event any Survey Materials or associated Optum intellectual property are exported by Licensee outside of the country in which Licensee is located, Licensee is obligated and solely responsible for ensuring compliance with all applicable import and export laws and regulations of the United States of America and/or any applicable foreign jurisdictions.

f. This Agreement and performance hereunder shall be governed in accordance with the laws of the State of New York, but excluding New York choice of law principles. With respect to any dispute arising in connection with this Agreement, Licensee consents to the exclusive jurisdiction and venue in the state and federal courts located in New York City, New York.

g. The terms and conditions of this Agreement supersede the terms of any license agreement embedded in the Software, or any purchase order.

h. Any format and/or language changes have the potential to affect the survey data received. Therefore, to maintain the validation and integrity of the SF Health Surveys, **no language or formatting changes** allowed. The format of the survey is scientifically engineered to facilitate accurate and unbiased data, as well as keeping the SF Health Survey in a visual format that is comprehensible to the patient/participant, including those who may be impaired and/or elderly. **Licensee must administer the survey in the exact format Licensed receives it in. The only item Licensee may add is a header with patient identification and / or administration information.** If Licensee wishes to add a header, contact Licensee's Account Representative. Do not use any forms Licensee may have received in the past.

i. Licensee agrees that not using all eight domain scales may compromise the validity of comparisons to norms and other interpretation guidelines.

Appendix Q

Email permission for the BATD-R

Lejuez, Carl Wilborne <clejuez@ku.edu>
Sun 13/05, 23:26
Lloyd Oates (16662517)

Lloyd,
Good luck with your work and thanks I've attached the manual and an article that may be helpful with your questions (please feel free to ask me any follow up questions as would be useful).
I've also attached a training video you might find helpful...https://www.dropbox.com/s/nuq3w071ry3z1v0/BW%20TrainingVideo%2011-18-10%20FINAL.mov?dl=0– 50 MIN
Best of luck.
Carl
****

Carl W. Lejuez, PhD
Interim Provost and Executive Vice Chancellor
University of Kansas
Strong Hall, Room 250
1450 Jayhawk Boulevard
Lawrence, KS 66045
clejuez@ku.edu
240.535.0467 (cell)

From: Lloyd Oates (16662517) [mailto:16662517@students.lincoln.ac.uk]
Sent: Sunday, May 13, 2018 3:58 PM
To: Lejuez, Carl Wilborne <clejuez@ku.edu>
Subject: BATD-R materials

Dear Professor Lejuez,

I am emailing you as I am currently developing my research thesis protocol for my studies. I am looking at exploring the use of a values based behavioural activation intervention for people with Secondary Progressive Multiple Sclerosis.

Having discovered the BATD-R I believe this manual could be beneficial for use in this population, due to the values assessment, structure, and the adaptability that has been demonstrated from the evidence base. I note that in the manual that you could be contacted for a modifiable manual suitable for patient use. I was wondering if with your permission I could have and use this.

I would also appreciate any thoughts or considerations in the use of the manual or explaining values to clients in a user-friendly way.

Best wishes

Lloyd Oates, Trainee Clinical Psychologist, Trent Doctorate in Clinical Psychology

Appendix R

BATD-R session scripts

The Revised Treatment Manual for the
Brief Behavioral Activation Treatment for Depression (BATD-R)

Session One

Session One Key Elements:

1. Confidentiality
2. Discussion of Depression
3. Introduction to Treatment Rationale
    - What about stressful life events and loss in your life?
4. Introduction to Daily Monitoring (Form 1)
    - Enjoyment and Importance Ratings
    - When should you complete the Daily Monitoring Form?
5. Important Points about the Structure of this Treatment

Discussion of Depression

This treatment was designed to help you with depression, which is defined as an extended period of time of at least two weeks in which a person experiences a depressed mood or a loss of interest or pleasure in activities that were once enjoyed, along with several other symptoms. Many people will experience at least one episode of major depression in their lifetime and it can affect people of all ages, cultures, income, education, and marital status. Depression can have a major impact on your life including decreased optimism/motivation, low self-esteem, trouble concentrating (paying attention), self-harm, and/or suicidal thoughts and behaviour. Medical problems associated with depression include heart disease, chronic pain, type 2 diabetes, substance use, fatigue, and malnutrition. Individuals with depression often keep to themselves and avoid their normal activities. This isolation can cause additional problems, such as loneliness, relationship problems, decreased job satisfaction or unemployment, and educational failure. Given all of these resulting problems, the identification and treatment of depression is critical.

The specific symptoms of depression may include:

- **Feeling sad or down most of the time**
- **Loss of interest in usual activities**
- **Significant weight loss or weight gain**
- **A decrease or increase in appetite**
- **Difficulty sleeping or sleeping too much**
- **Feelings of agitation or irritability**
- **Feeling tired or loss of energy (fatigue)**
- **Feelings of worthlessness or excessive / inappropriate guilt**
- **Difficulty thinking or concentrating or making decisions**
- **Crying spells**
- **Feeling hopeless**
- **Suicidal thoughts and/or attempts**

Although most individuals experience some form of the above symptoms from time to time, a diagnosis of depression only is made if you feel strong feelings of distress, or you are having a lot of trouble with your day-to-day functioning. Some people can identify stressful life events including loss of a loved one, financial difficulty, or job loss as a reason for their depression. However, the specific causes of depression are rarely known, and depression might start without warning. Regardless of the initial cause of depression, depression results in a specific pattern of behavior that leads to feelings of loneliness, sadness, isolation, lack of purpose, and/or hopelessness. The key to feeling better is not in identifying the root cause of depression because this is nearly impossible, but rather in understanding and changing your depressed patterns of behavior.

Introduction to Treatment Rationale for Behavioral Activation

Treatment will involve an approach called behavioral activation. According to this approach, the key to a depression-free life is to develop healthier patterns of behavior where each day contains important and/or enjoyable activities that help you feel fulfilled and as if your life has purpose. Once you have identified the areas of your life you want to focus on and your values within those areas, we will begin to identify and plan daily activities that help you to live according to the values that are most important

to you. This is important because when you accomplish activities that are closely linked to what you value in life, you are more likely to have positive and enjoyable experiences, which will improve how you feel and think about your life. It is difficult to feel depressed and hopeless if you are regularly doing activities that you feel are valuable and worthwhile and that bring you a sense of pleasure and accomplishment.

This manual targets changing your behavior as a method for improving your thoughts, feelings, and overall quality of life. Many individuals with depression often feel tired and lack the motivation to do various activities; thinking that once they have more energy and think more positively, they will be able to do the activities they have ignored or have been unable to accomplish in the past. The opposite approach is taken in this treatment – behavior is changed first as a way to increase energy and motivation, as well as positive thinking and feelings. The focus on behavior change, however, does not mean that we ignore thoughts and feelings. Instead, we suggest that negative thoughts and feelings will change only after you change your behavior and are having more positive life experiences. Healthy behavior is defined as behavior that is directed towards improving your quality of life, and is directed towards the attainment of the values you have in your life. In contrast with healthy behavior, unhealthy (depressed) behavior generally is not directly related to improvements in the quality of your life and does not move you closer to living according to your values.

You should know that it is possible for you to be active, yet still be depressed. This can happen if you feel overwhelmed with activities that are unfulfilling or forced by others. For example, although you may be busy at work and home, these activities may be focused only on helping others. Although it certainly is important to help others, it is never a good idea to focus so much on others that your own needs and feelings are completely neglected. Focusing entirely on the needs of others may result in feelings of emptiness and dissatisfaction, followed by confusion and guilt for having such feelings. Thus, it is not only important to have many activities in your life, but specifically to have activities that bring you some degree of pleasure and fulfillment.

What about stressful life events and loss in your life? Often people who have experienced stressful life events and loss end up having long standing feelings of depression. After something very bad has happened or loved ones are lost, life can feel empty, or meaningless. It can feel as if there is very little to live for and that all the support and happiness you once had is gone forever. Thoughts and bad dreams may

keep coming back about the bad experience or about the loved one who has passed away. In this treatment, it is very important for the therapist to understand what happened to you, how you felt about it, and most importantly, how it affects your life now. At every session, we will spend some time talking about events in your life that have led to your depression. However, this treatment requires more than just talking about what has happened. In addition, we also will spend some time trying strategies that will help you to live a more fulfilling and meaningful life going forward. Nobody can change events of the past, but we can plan for a better future by what we do today. Often when people have experienced stressful life events and loss, negative thoughts and feelings about the event come to mind all the time. It becomes hard not to think about it or feel terrible that it happened. We find that it is important to understand how these experiences impact your current behavior. Often after a loss or stressful life event, people change how they spend their time, and this can lead to depressed behavior patterns. For example, you might find it difficult to sleep at night, and so you spend a lot of time sleeping during the day. If you sleep during the day, you may be unable to perform important daily activities or lack the energy and desire to socialize with family and friends. This treatment will help you to identify activities that might be making your depression worse, and can help you modify or change those activities so that you feel depressed less often. After a loss or stressful event, it can often take time and focus to decide how you want to live your life moving forward, and this treatment is designed to help you with that. The goal is to help you make the best life possible for yourself. This can be hard work, but if you trust the process you will find that good things will come from your effort. We will work at a pace that is comfortable for you. Are you willing to work on this together?

Daily Monitoring Form

Because the main focus of this treatment is increasing your healthy behavior, it is important to become aware of what you do each day. Although you probably have a an idea of how you spend your time, we really need exact information about what you are doing each day. To that end, we would like you to spend the next week writing down all of your activities. This is useful for several reasons. First, it will help us to identify the pattern of your depressed behaviors and moods. Every person is different, so it is important for us both to see how depression is affecting your daily activities. Being aware of your patterns might motivate you to increase your healthy activity level.

Second, this will provide us a measure of your current activity level which we will then be able to compare with your activity level later in treatment, after you use the treatment strategies. Finally, a close look at your daily routine might lead you to develop some ideas about where you might consider adding some healthy activities to each day. To monitor your current activities, you keep a detailed log (hour by hour) of all activities that you do, including those that seem insignificant, such as sleeping or watching television. You will use the Daily Monitoring Form to record your activities. You will need to complete one form for each day. For now, just do things as you normally would do them. Your only task is to write down your activities, trying to be as accurate and as thorough as you can.

Enjoyment, Importance, and Achievement Ratings. Once you have recorded the activity, you then rate the activity in terms of three things: Enjoyment, Importance, and Achievement. For the Enjoyment rating, think about how much you enjoy the activity. In other words, think about how much fun or pleasure you have when you are doing the activity. You will use a scale from 0 to 10 to rate Enjoyment. A rating of 0 will be for activities that you do not enjoy at all. A rating of 10 will be for activities that you enjoy very much. For example, going to a picnic might be considered a very enjoyable activity and be assigned a rating of 10, whereas washing the dishes might be considered no fun at all and be assigned a rating of 0.

For the Importance rating, think about how important in your heart it is to have this activity in your life. On a scale from 0 to 10 rate each activity, with 0 meaning that the activity has no importance at all and 10 meaning that the activity is of the highest importance in your life. For example, going to work is probably a very important activity in your life because it is your source of income to support your family. You might give your work a rating of 10. On the other hand, watching television is probably a less important activity in your life. You might give watching TV a low rating such as a 2.

For achievement think about how difficult the task may have been. This is not a rating of how hard a task is generally, but a rating of how hard it was for you on the day, and therefore how much effort it took. Once you have thought about the task in this way, which may have been hoovering one room, but you found it difficult to motivate

yourself, or became tired, think about what sense of achievement you had despite these barriers.

Consider for a moment that some activities might be very important but not very enjoyable, and other activities might be very enjoyable but not very important. For instance, washing clothes might be high in importance but not very enjoyable, whereas watching a favorite TV program might be very enjoyable but not very important. Meanwhile some activities may be rated as high on both enjoyment and importance and others as low in enjoyment and importance. For example, eating dinner with family might get rated as a 9 in enjoyment and importance because it is both very enjoyable and important. On the other hand, lying in bed in the afternoon might be rated a 0 in both enjoyment and importance because it is neither important to your life nor very enjoyable. In addition to enjoyment and importance ratings for each activity, you also should provide a single rating for your overall mood for the day at the bottom of the form. The rating should be between 0 for the most negative mood and 10 for the most positive mood. You don't have to rate your mood for each hour of the day, just a general rating of your mood for the day.

When should you complete the Daily Monitoring Form? To complete your Daily Monitoring Form, you might choose to record your activities as you go through your day or you might prefer to wait until the end of the day to do so all at once. You may do whichever you prefer. However, it is best to record your activities on the day that they occurred, as opposed to several days later. For example, on Wednesday it will be difficult to remember the activities you did on Monday. We will spend a lot of time reviewing your Daily Monitoring Forms each week, so be sure to complete and bring the completed forms to each session.

Important Points about the Structure of this Treatment

Before we finish today, it is important to understand that this is a structured treatment. This means that treatment involves a series of steps. Depression is a problem that builds over time, so it is not possible for it to overcome it in a few days or after just one or two visits. It takes some work and it is very important to practice all of the strategies we will review in this treatment. Although you may notice some immediate benefits in the first few sessions, only coming to a small number of sessions may not be helpful in the long-term. We realize that sometimes unforeseen events can arise that

might cause you to miss a session, and this is understandable, but we urge you not to cancel a session because you are feeling depressed, tired, or unmotivated. Most people find that even when they are feeling depressed before a session, they are likely to feel much better after the session. This idea of motivating yourself to take positive steps like attending treatment sessions even when you are feeling depressed, tired, or unmotivated is an approach that will help you tremendously in this treatment and in overcoming depression.

In addition to the importance of regular attendance, these sessions will include both assignments for you to complete during our session and assignments for you to work on at home. Completing the homework assignments is very important for progress as we find that people who regularly complete the homework assignments see the most improvement in their lives. If you find any homework assignments difficult or overwhelming, we can discuss this and come up with ways to make it easier for you to do. It is very important that we work together to make sure that this process feels comfortable and useful to allow you to complete these important assignments.

Assignments:

1. Complete Daily Monitoring Form

Session Two

Session Two Key Elements:

1. Daily Monitoring: Review Assignment (Form 1)
    - Troubleshooting
2. Treatment Rationale: Review
3. Complete Life Areas, Values, and Activities Inventory (Form 2)

Daily Monitoring: Review Assignment (Form 1)

We will begin this session by reviewing your Daily Monitoring Forms (Form 1) from the past week. Notice the types of activities you are doing and if they are enjoyable, important, both, or neither. Often people with depression find themselves spending very little time in activities that are enjoyable. They often will also withdraw from activities that are important to them. We should discuss your level of activity and how often you are doing enjoyable and important activities. In the next few sessions, we will focus on making changes in your daily activities, but right now do not try to change anything. Instead, just pay attention to what your life is like every day, what you are doing, and to what extent these activities are leading you to feel better or worse.

Troubleshooting. Some people find it difficult to complete the Daily Monitoring Forms. If you have not been able to complete this form in the past week, it first will be important to understand why. One reason it may be difficult to complete the monitoring is that you may feel you already have a good sense of how you spend your time and that it would not be useful to write activities down. You can probably recall a lot of things you have done in the past week, but there may be quite a few activities that you might have forgotten about by now. Having your daily activities recorded on paper for each day can be helpful for both me and you to identify those depressed patterns that we discussed last session. Many people are very surprised by patterns they notice on the forms and begin to gain a real understanding of how certain patterns lead to more depressed feelings, whereas others lead to more positive feelings. Having these forms for the session allows our work to be more efficient by allowing us a clear sense of exactly how you are spending your time moment-to-moment without having you try to recall all of that information in the session.

A second reason it may be difficult to complete the monitoring is that you may feel like it is an overwhelming task. Writing down all of your activities of the day can feel like a lot of work, but in the end you are likely to find that what you learn is well

worth the effort. One way to make this easier is to keep your recordings as brief as possible (e.g., “lunch,” “took kids to school,” “cooked dinner”). Another way to keep this easier is to complete the form at the end of the day. Finally, if you find it extremely challenging to do the forms at all, you might consider initially doing the forms for 2 or 3 days of the week (being sure to include both week and weekend days), and then gradually increasing the number of days each week that you complete the forms. You are likely to find that once you get into the habit of doing the forms, it will seem less burdensome. People who have some difficulty writing and/or reading also may find the forms difficult to complete. If this is the case, a modified form that does not require writing or reading is available.

If you were not able to complete any Daily Monitoring Forms for the past week, it is not recommended that you attempt to remember the entire week right before the session or in the session with your therapist. Remembering the necessary level of detail will be too difficult and with so much information missing it will be difficult to detect any consistent behavior patterns. Instead, you should complete a form right now in session for the past day or two. You will likely be able to recall most of your activities from today and one or two days ago. Even though it is only one or two day’s worth of activities, it is a starting point and you and we can begin to look for behavior patterns. Completing the forms for each day of the coming week will increase the chances of making good progress.

Treatment Rationale: Review

Review Treatment Rationale as needed using content from Session 1.

Life Areas, Values, and Activities (Form 2)

Life Areas. An important step in this treatment involves thinking about the most important areas of your life. Think for a moment about each of the following life areas.

1. **Relationships:** This life area refers to the part of your life that involves family, friends, and/or your romantic partner (for example, your spouse, boyfriend, or girlfriend).
2. **Education/Career**: This life area refers to time spent developing your education and your career. This can include formal education such as college or a trade school, but could also be informal such as reading books on a particular topic. It also includes working at your current job or finding a new job.
3. **Recreation/Interests**: This life area refers to leisure time, when you can have fun

and/or relax. It also may include doing things for others such as volunteering.

4. **Mind/Body/Spirituality:** This life area refers to both physical and mental health as well as religion and/or spirituality.
5. **Daily Responsibilities:** This life area refers to your obligations and responsibilities to others and your belongings.

Values. Once we have considered these different life areas, we move to identifying your values in each of these areas. A value is an ideal, quality, or strong belief in certain way of living.

In other words, what is important to you about each of these life areas? What are you striving to be in each life area? What are the qualities of that life area that are important to you? A value is something that is important to you, in your heart, about that life area. Be sure that the values you identify are very personal to you, and not necessarily the values of other people in your life or society in general.

Activities. A primary goal of this session is to identify key values from each life area and translate them into activities. Life areas are the important parts of your life, values are how you want to live your life in each of those areas, and activities are things you can do to actually live according to the values. Become more aware of your values and using them as a guide to selecting your activities is key to this treatment. However, without the activities that help you live according to your values, the values are just words and ideas, and not a reality. Please see the examples of life areas, values, and activities provided in Appendix 1.

The Life Areas, Values, and Activities Inventory allows you to turn your values across key areas of your life into reality. For each life area, you have space for both values and activities (you can add extra blank sheets for each life area to add additional values and activities). Each activity should be something that you might do to live consistently with the value that you identified. For example, if “being a good husband/wife” is something you value, list some activities that you think are consistent with being a good husband/wife. Possible activities might include planning a date with your husband/wife once a week or helping your husband/wife with a household chore she/he dislikes. When selecting activities it is important to remember that the activity must have two specific characteristics: they should be both observable by others and measurable. Therefore, "feeling better" is not what we mean by activity, but “eating dinner with my mother twice a week” would be

appropriate. This latter activity could be observable and measurable in the sense that you could meet with her twice per week. The activity should also be broken into its smallest piece. For example, if an activity is going for a bike ride, consider that a number of intermediate steps are required before one can do this. Such steps might include, bringing the bike up from the basement, checking the air in the tires, finding a tire pump, pumping the tires, etc. So the first step in the activity of going for a bike ride might just include checking that the bike is in good shape, with later weeks including the actual ride. Activities are far easier to accomplish if they are broken into the smallest pieces possible. Thus, if these three conditions (observable, measureable, smallest piece possible) are met, you have identified an acceptable activity.

Sometimes it is tempting to select very difficult activities for which the benefits are in the future and not a guarantee. For example, getting a college degree is a long-term goal that may take some time to achieve. It's important to have these types of goals, but it's even more important to be clear about the rewarding activities that are a part of achieving that long-term goal. This might include activities that get you to the goal but are important and/or enjoyable on a daily basis such as studying a topic you enjoy or having a discussion about something you learned in a class. Therefore, you should select activities across a range of difficulty, with only a few being smaller steps toward more difficult long-term projects. To improve the likelihood of initial success and to help you start this program, some of the activities you choose should be activities you already are doing regularly but would like to increase in frequency or duration (see your Daily Monitoring Forms for assistance). We will now complete this form together and you will continue adding to it and editing it for homework.

Assignments:

1. Complete Daily Monitoring (Form 1)
2. Review and Edit Life Areas, Values, and Activities Inventory (Form 2) – today we have thought about a few values, but they can be really hard to identify when we have not thought about them before. I will email a list of examples values to help you review the work we have done today.

Session Three

Session Three Key Elements:

1. Daily Monitoring: Review Assignment (Form 1)
2. Life Areas, Values, and Activities Inventory: Review Assignment (Form 2)
3. Activity Selection and Ranking (Form 3)

Daily Monitoring: Review Assignment (Form 1)

We will begin this session by reviewing your Daily Monitoring Forms (Form 1) from the past week. Notice the types of activities you are doing and if they are enjoyable, important, both, or neither. Often people with depression find themselves spending very little time in activities that are enjoyable. Some people withdraw from activities that are important to them and end up spending long periods of time during the day in activities that are neither enjoyable nor important. In this case, you may find it hard to find any activities that are rated high in either enjoyment or importance. On the other hand, some people with depression have many important activities in their week but very few that are enjoyable. These people often spend a lot of time working, taking care of others, and meeting various obligations to the exclusion of any time spent on self-care or pleasurable activities. For many people with depression, their important activities are not very enjoyable. How would you describe your activities? How often are you doing enjoyable and important activities? Today, we will focus on making changes in your daily activities.

Life Areas, Values, and Activities Inventory: Review Assignment (Form 2)

From last session you have learned about life areas, values, and activities. For example, the life area of "Education/Career" and the related value of "getting a college education" might include specific actions such as identifying a school, speaking to an enrollment counselor, enrolling in classes, etc. As another example, the life area of "family relationships" and the value of "developing a closer relationship with a particular family member" may include specific actions such as eating dinner together every Saturday, talking on the phone twice a week, or offering specific assistance (for example, baby sitting). Although completing activities aimed at one specific life area and value can be satisfying, it is important to select activities across a wide range of life areas because depression is rarely the result of only one aspect of your life. For example, someone with depression might think that if they could only get a certain job, they would not be depressed anymore. As a result, all of their focus might be on would

be activities that have to do with getting that job. In this situation, it would certainly be helpful to work on activities related to the job, but it is just as important to work on activities tied to other life areas. Living a fulfilling life is not about getting a certain job, achieving a certain body weight, being with one particular person and no other, or having a specific amount of money. By narrowing your focus on one aspect of your life, you limit your opportunity to have positive experiences and feel fulfilled in other areas. Ultimately, this can worsen your depression, especially if the goals you have in mind require a long period of time or are extremely difficult to obtain. Finally, be sure that you have both "enjoyable" and "important" activities in your plan, with emphasis on the type of activity that is less frequent in your Daily Monitoring Forms. Throughout treatment be sure to keep thinking about values in each life area and to generate new activities in line with these values.

Activity Selection and Ranking (Form 3)

By now, you will have identified many activities for each of the values in your life areas. Today, we will pick some activities to use as a starting point. As you select an activity, add it to the left column of Form 3 (Activity Selection and Ranking). Remember that the activities should be observable, measurable, in their smallest pieces, and directly relevant to the values you listed in the Life Areas, Values, and Activities Inventory (Form 2). The more your daily activities are linked to your values, the more likely you will experience the activities as both pleasurable and meaningful and the more you will feel that you are living the life you want to live. This is extremely important to pay attention to because there is no reason to busy yourself with activities that do not make you feel that you are living a richer, more meaningful life. Once you have your activities listed on Form 3, rank them from 1 (easiest to accomplish) to hardest to accomplish on the right column of Form 3. One way to do this is to first identify the easiest and assign it a 1 and then to identify the most difficult. From there, try to fill in the others. In activity planning, you will start with the easiest activities and gradually work towards the more difficult ones.

Daily Monitoring with Activity Planning (Form 1)

Once you have identified the target activities, you will need a plan for how you will include these activities in your daily schedule and how you will monitor your progress. We will use your Daily Monitoring Forms for the upcoming week to help you plan your new activities. Your opinion will be critical in deciding how many activities

to select and it is important that you challenge yourself without becoming overwhelmed. The simplest approach is usually to start with 1-3 of the easiest activities. We will begin now by identifying activities for the coming week and entering these activities into the blank Daily Monitoring Forms for each day at the time that you plan do them. For example, if your activity is "play with your daughter" you might enter that activity (Form 1) at 11am on Monday, 10am on Wednesday, and 9am on Thursday.

Be sure to seriously consider whether you are ready for a particular activity and consider barriers that you might encounter. If there are barriers to doing the activity, we should discuss steps you might take to first overcome those barriers. Remember in previous sessions when we discussed breaking activities down into the smallest pieces possible? When you run into difficulty with an activity it can be useful to consider if you really have broken the activity down far enough. For example, if your activity is to go to the gym twice a week, you first might have to buy clothing, research gyms, find a partner to go to the gym with, or arrange for transportation. In this case, "going to the gym" may not be the smallest piece of this activity. You should add any additional activities to overcome these barriers on Form 2 (Life Areas, Values, and Activities Inventory). A key aspect of this treatment is to plan the specific day and time that you will do each activity. This will require you to really think through where you can realistically fit the activity into your schedule. By doing this, you will find that you are more likely to accomplish the activity.

During the upcoming week, you will complete the Daily Monitoring Form just as you have been doing each day. However, circle each planned activity in your form if you completed it. Be sure to give it an enjoyment, importance, and achievement rating at this time too. This is important because it will allow us to see if you experienced the activity as more or less enjoyable or important than you originally thought. If you did not complete the activity at the scheduled time, put a line through it (but do not erase it) and write in the activity you did accomplish at that time. If possible, try to re-plan the missed activity for another time that week (or even that day) and be sure to circle it if you complete it. We will review your Daily Monitoring Forms next week as usual, but this time we will look for the circled activities you planned, how enjoyable and important they were, and if you encountered any problems trying to accomplish them. We can work together to address whatever challenges arise.

When you begin to complete your activities, you will begin to move toward the values you have set out for yourself in important life areas and you will be living a fuller life

and feeling less depressed. The key is to not focus too much on whether you have succeeded at accomplishing the values but instead it is to focus entirely on completing the daily activities that come directly from your values. Many values require a lifelong effort (e.g., being a good parent) where you constantly try to live in a way that is consistent with your values. For this reason, values are not considered an endpoint of a process, but instead they are a guide throughout the process, proving information about how we want to live our lives and helping us to choose the activities are the vehicles that help us move in the direction of our values.

Assignments:

1. Daily Monitoring (Form 1)
2. Continue to Review and Edit Life Areas, Values, and Activities Inventory (Form 2)
3. Review and Edit Activity Selection and Ranking

Session Four

Session Four Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1) ____
2. Getting help from others
3. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____
2. Continue Adding/Editing Contracts (Form 4) ____

Daily Monitoring with Activity Planning: Review Assignment (Form 1)

Let's review your forms of Daily Monitoring with Activity Planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How enjoyable and important did you find them? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and couldn't complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities.

Your chances of overcoming depression are much improved when you have support from others for your healthy activities. Family and/or friends can be a great

support in our lives, but sometimes they may be more likely to notice your depressed behaviour than your healthy activities. Other times, supportive people would like to help but they either do not know how or they tend to do things that they think are helpful but are not actually helpful. For example, sometimes friends or family take over your responsibilities because they see what a hard time you are having now or instead, they may nag or push you to do things you are not ready to do. In both cases, the support person wants to help, but is doing things that are not helpful.

It would be helpful to ask people for help for your healthy activities in the ways that you need it. Let's think about some activities that would be easier with support and let's think about who could help you. We do this because you might find that going shopping once per week is difficult because of mobility. In this case we could think about who could help you with shopping. Additionally, you might find shopping really boring. In this case, going with others might make it more enjoyable.

The next step is to tell each person what you are trying to accomplish and exactly how they can help. You might learn that involving others in your activities makes the activity not only more likely to occur but also more enjoyable. Involving others can also strengthen your relationships. All of these things will have a positive impact on the way you feel every day.

Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Based on our discussion this session, you should now plan your activities for the next week. If you are able, try to plan for one or more new activities for the upcoming week in addition to the activities you accomplished the previous week.

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Session Five

Session Five Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1)
2. Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2)
3. Activity Selection and Ranking: Concept Review and Edit (Form 3)
4. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring with Activity Planning: Review Assignment

Let's review your forms of Daily Monitoring with Activity Planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and couldn't complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities.

Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2)

Today, we will review the concept of values to make sure that the activities that you are accomplishing still seem consistent with the values you mentioned earlier in

treatment. Remember, an important step in this treatment approach involves determining the activities you would like to add to your life. Although becoming more active in life is important, we need to be sure that the activities that you select are ones that are enjoyable and/or important to you and that make you feel like you are living the life you want to live. One way to help identify activities that are important to you is to think about what you value in life. Let's revisit each of the life areas and the values you have in these areas. Remember, a value is something that is important to you in your heart about that life area. Review your values for: Relationships, Education/ Career, Recreation/Interests, Mind/Body/Spirituality, and Daily Responsibilities. Think about how much the activities you have identified in the last few weeks fit into your values. Are there new values that have come to mind? Are each of the activities consistent with the values you mentioned?

Activity Selection and Ranking: Concept Review and Edit (Form 3)

Throughout treatment, you may have added, subtracted, or changed activities in your Activity Selection and Ranking Form (Form 3). We can take some time to review how to go about selecting activities to add (as well as activities to remove or change) in Form 3. In general, if you believe that completing a particular activity would bring a sense of pleasure and/or accomplishment, then it probably would be good to include it. It is also important to decide which life are and value each activity is associated with. This is a good reminder to revisit the activities on your list and to think of the relevant life values. Also, when selecting activities it is important to remember that they must be observable by others, measurable, and broken into the smallest piece. For example, "being a better daughter" is not an activity that you could plan, but "offering to help mom make dinner twice a week" would be appropriate. If these conditions are met, you have identified an appropriate activity. Although it is sometimes tempting to select very difficult activities for which the benefits are very delayed or uncertain. For example, having your own home is a long-term goal. To address this potential problem without limiting your ambition, break activities into small steps and select activities across a range of difficulty, from easy activities you are currently doing to extremely difficult activities that will take some effort.

Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Based on our discussion this session, you should now plan your activities for the next week. If you are able, try to plan for one or more new activities for the upcoming week in addition to the activities you accomplished the previous week.

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Evaluation and Beyond Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1)
2. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)
3. Preparing for the End of Treatment

Daily Monitoring with Activity Planning: Review Assignment (Form 1)

Let's review your forms of Daily Monitoring with Activity Planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and couldn't complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities.

Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Once again, plan for 1-2 additional activities

Preparing for the End of Treatment

We have done a lot of great work together throughout treatment and you have accomplished so much. When we look back at your Daily Monitoring (Form 1) from the first week of treatment and compare them to your Daily Monitoring with Activity Planning (Form 1) from the last week of treatment, what do you see? It is important to identify your patterns of behavior now but also at the start of treatment which will help you know what patterns to look out for in the future.

At this point, you have learned a number of skills that can help you feel better and live healthier when you begin to feel depressed again. You are strongly encouraged to consider continuing to use these forms to monitor and plan, especially in the next few weeks. Eventually you may find you are living consistent with your values on a daily basis without having to use the forms to monitor and plan, but you might find it helpful to review this manual and practice all of the skills again should depressed feelings return.

Of course, it is possible that feelings of depression could return, but you should remain aware that depression is far less likely to persist when you live a healthy, meaningful, and fulfilling life. No matter what has happened in the past, it is possible to make changes to our lives, to make the best of circumstances, and spend time doing activities that fill your life with purpose and meaning.

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Appendix S

Resource pack from the BATD-R

Daily monitoring diary

Time	Activity	Enjoyment (0-10)	Importance (0-10)	Achievement (0-10)
5-6 am				
6-7 am				
7-8 am				
8-9 am				
9-10 am				
10-11 am				
11-12 am				
12-1 pm				
1-2 pm				
2-3 pm				
3-4 pm				
4-5 pm				
5-6 pm				
6-7 pm				
7-8 pm				
8-9 pm				
9-10 pm				
10-11 pm				
11-12 pm				
12-1 am				
1-2 am				
2 → 5 am				

Overall Mood for the day (0-10)

Life Areas, Values, and Activities Inventory

Life Area (1/5): <u>Relationships</u>

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Form 2. Life Areas, Values, and Activities Inventory
Life Area (2/5): Life Area: Education/Career

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Form 2. Life Areas, Values, and Activities Inventory
Life Area (3/5): Life Area: Recreation/Interests

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Form 2. Life Areas, Values, and Activities Inventory
Life Area (4/5): Life Area: Mind, Body, & Spirituality

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Form 2. Life Areas, Values, and Activities Inventory
Life Area (5/5): Life Area: Daily Responsibilities

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Value:	**Enjoyment (0-10)**	**Importance (0-10)**	**Achievement (0-10)**
• Activity 1:			
• Activity 2:			
• Activity 3:			
• Activity 4:			
• Activity 5:			

Activity Selection and Ranking

Instructions: List your desired 15 activities and rate the difficulty of each from 1 = least difficult to 15 = most difficult.

ACTIVITY	RANK

Appendix T

Adherence Checklist

Session One (Home)

Session One Key Elements:

1. Confidentiality ___
2. Discussion of Depression ____
3. Introduction to Treatment Rationale ____
    - What about stressful life events and loss in your life? ____
4. Introduction to Daily Monitoring (Form 1) ____
    - Importance, Enjoyment and Achievement Ratings ____
    - When should you complete the Daily Monitoring Form? ____
5. Important Points about the Structure of This Treatment ____

Assignments:

1. Complete Daily Monitoring Form ____

Session Two (Values)

Session Two Key Elements:

1. Daily Monitoring: Review Assignment (Form 1) ____
    - Troubleshooting ____
2. Treatment Rationale: Review ____
3. Complete Life Areas, Values, Activities Inventory (Form 2) ____

Assignments:

1. Complete Daily Monitoring (Form 1) ____
2. Review and Edit Life Areas, Values, and Activities Inventory (Form 2) ____
3. Review Appendix 1: Moving from Life Areas and Values to Activities ____

Session Three (Int 1)

Session Three Key Elements:

1. Daily Monitoring: Review Assignment (Form 1) ____
2. Life Areas, Values, and Activities Inventory: Review Assignment (Form 2) ____
3. Activity Selection and Ranking (Form 3) ____
4. Daily Monitoring with Activity Planning (Form 1) ____

Assignments:

1. Daily Monitoring (Form 1) ____
2. Continue to Review and Edit Life Areas, Values, and Activities Inventory (Form 2) ____
3. Daily Monitoring with Activity Planning for upcoming Week (Form 1) ____

Session Four (Int 2)

Session Four Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1) ____
2. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____

Session Five (Int 3)

Session Five Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1) ____
2. Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2) ____
3. Activity Selection and Ranking: Concept Review and Edit (Form 3) ____

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____

Evaluation

Session Nine Key Elements:

1. Daily Monitoring with Activity Planning: Review Assignment (Form 1) ____
2. Preparing for the End of Treatment ____

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1) ____

Appendix U

Interview schedule

Title of Study: Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)
IRAS Project ID: 254182
Name of Researcher: Lloyd Oates

Interview schedule

Behavioural Activation for Low mood in Multiple Sclerosis (BALMS)

Post intervention interviews will be structured and guided by Elliott and Timulak's (2005) Change Interview Outline:

1. What has therapy been like for you?
2. What changes, if any, have you noticed in yourself since therapy started?
3. What changes have you noticed in your levels of depression?
4. In general, what do you attribute these various changes to?
5. What personal strengths or aspects of your current life situation have helped you make use of therapy to deal with your problems?
6. What things about you or your life situation have made it harder for you to use therapy to deal with your problems?
7. What have been the most helpful things about your therapy so far?
8. What kinds of things about the therapy have been hindering, unhelpful, negative or disappointing for you? Was there anything that was difficult or missing from your treatment?
9. What has been like for you to be involved in this research?
10. What changes have you noticed in your quality of life?
11. What changes in fatigue levels have you noticed?
12. What were the best parts of the intervention?
13. What were the worse parts of the intervention?
14. Do you feel there were any other possible explanations for the changes in your depression/anxiety/quality of life? If so, what?

Poster

Background

People with secondary progressive multiple sclerosis (MS) experience high rates of depression.[1]

Depression may result from illness-related challenges, which reduce opportunities to engage in or find new enjoyable activities.[2,3,4]

Cognitive Behavioural Therapy (CBT) has demonstrated reduced rates of depression in people with MS, but cognitive difficulties in those with secondary progressive MS may be a barrier to engagement.[5]

Behavioural activation may represent an accessible therapeutic intervention for this group. Behavioural activation is as effective as CBT in those without MS.[6]

Aims

- Examine preliminary evidence of efficacy of a behavioural activation intervention, for people with secondary progressive MS experiencing low mood
- Examine impact on mood, fatigue, and quality of life (QoL)
- Understand participants' experience of the intervention

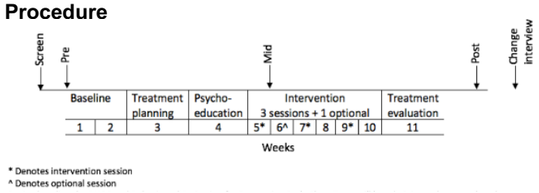
Method

Design
Mixed method, single case experimental design.

Participants
Individuals with secondary progressive MS and depression (≥ 8 on the Hospital Anxiety Depression Scale – depression subscale; HADS).

Measures
Depression: HADS
Activation: Behavioural Activation for Depression Scale – Short Form (BADS-SF)
QoL: Short Form – 12 version 2 (SF-12v2)
Values: Engaged Living Scale (ELS)
Fatigue: Modified Fatigue Impact Scale – Short Form (MFIS-SF)

Procedure

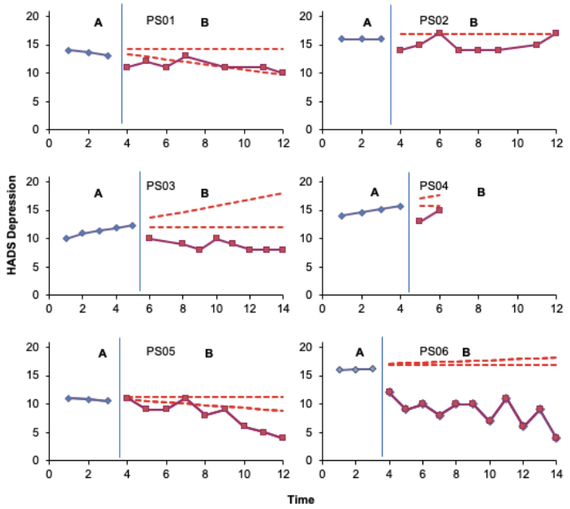


Baseline phase 2-4 weeks, followed by 5 sessions of behavioural activation using the BATD-R manual via telephone or Skype,[7] followed by change interviews.

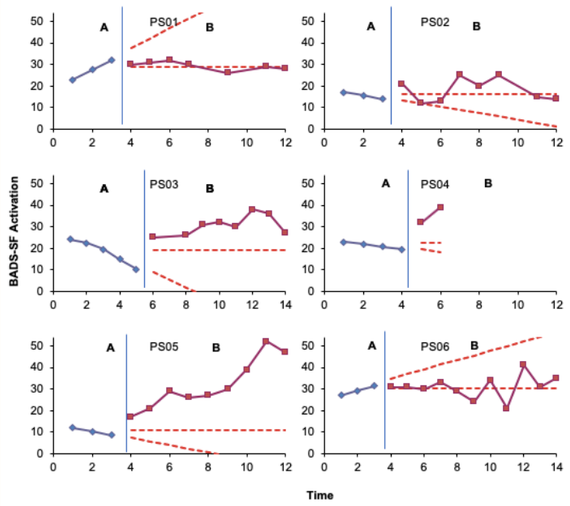
Data Analysis
Visual analysis using conservative dual-criterion and percentage exceeding the median.[8,9] Complemented with

Results

Depression



Activation



Recruitment
Eight people were recruited, of which six established a stable baseline and proceeded to intervention. Five participants completed intervention and change interviews. One participant withdrew.

Depression
Systematic reduction in depression was observed in two participants (PS03 & 06).

Three participants (PS01, 03, & 06) demonstrated highly effective treatment (≥.9) and two participants (PS02 & 05) demonstrated moderately effective treatment (0.7-0.9).

Reliable and clinically significant reduction in two participants (PS05 & 06).

Activation
Overall, activation scores appeared to covary with depression scores.

Systematic increase in activation was observed in two participants (PS03 & 05).

Two participants (PS03 & 05) demonstrated highly effective treatment (≥.9), and two participants (PS01 & 06) demonstrated moderately effective treatment (0.7-0.9).

Reliable change in one participant (PS05).

QoL
Two participants reported reliable improvement for mental health related QoL.

Values
Reliable and clinically significant improvement in two participants (PS05 & 06). Reliable deterioration in one participant (PS03).

Fatigue
No changes were reported in fatigue or physical health related QoL.

Feedback
Some participants reported benefits from the intervention and that it was acceptable, even in the face of competing demands.

Discussion

There was some evidence to suggest behavioural activation led to a reduction in depressive symptoms when engagement in positively reinforcing behaviour increased. Despite increasing activities to engage in positive reinforcement there were no adverse effects to individuals' mental or physical health.

Our findings are comparable to behavioural activation approaches used with individuals with other neurological conditions to reduce depression.[12] When considering that the treatment approach was predominantly self-directed and short-term in nature, the intervention is promising for those with secondary progressive MS.

Based on the results using both conservative dual-criterion and reliable change indices, the criteria to satisfy replicability allows us to conclude that the processes are demonstratable across cases, but with caution.[13]

Based on beneficial findings for some participants, further investigation is warranted. There is

Small Scale Research Project

Deprivation, access, and outcomes in health psychology treatment

Lloyd L Oates[1,2] and Nick Firth[3,4]

6. Trent Doctorate in Clinical Psychology, University of Lincoln, UK.
7. Lincolnshire Partnership NHS Foundation Trust, Lincoln, UK.
8. Derbyshire Community Health Service NHS Foundation Trust, Chesterfield, UK.
9. School of Health and Related Research, University of Sheffield, UK.

Lloyd Oates - Email: 16662517@students.lincoln.ac.uk Telephone: +44 (0)1522 886029
Nick Firth – Email: nick.firth@gmail.com

Correspondence: Lloyd Oates, Doctorate in Clinical Psychology, School of Psychology, College of Social Science, University of Lincoln, Sarah Swift Building, First Floor, Brayford Pool, Lincoln, LN6 7TS.

Acknowledgements

We would like to thank Drs Nima Moghaddam and Rachel Holt for their constructive feedback in regard to the focus and concept of the evaluation during its design and analysis.

DOI: 10.1108/MHRJ-02-2020-0010
https://doi.org/10.1108/MHRJ-02-2020-0010
Mental Health Review Journal

Abstract

Purpose
Individuals living in areas of higher deprivation are more likely to have requested mental health treatment but are less likely to have received treatment or benefitted from it. Less is known about the extent of access equality and treatment outcomes for individuals with a long-term health condition who experience mental health difficulties. The study aimed to evaluate the extent to which the neighbourhood Index of Multiple Deprivation predicted access to treatment, appointment attendance, treatment completion, and clinical outcomes in a British health psychology clinic.

Design
Retrospective data were used from 479 individuals referred to a health psychology clinic over 12-months. Clinical outcomes were measured using the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM). Patient data were linked with their neighbourhood Index of Multiple Deprivation decile. Data were analysed using correlation, linear regression, and Fisher's exact test.

Findings
There were no significant associations between deprivation and whether an individual attended assessment, attended treatment, or completed treatment, or between deprivation and patients' clinical outcomes. Exploratory evidence indicated that individuals from higher deprivation neighbourhoods may be over-represented in clinic referrals, and individuals from lower deprivation neighbourhoods may be under-represented, compared with local population distribution estimates.

Originality
This evaluation provides insights into treatment outcomes and deprivation in those with physical health difficulties. Further evaluation using a larger sample and comparing referrals with local prevalence estimates of comorbid mental and physical health problems would enable greater confidence in the conclusion that no evidence of inequality on the basis of neighbourhood deprivation was found.

Key Words: Deprivation, Psychological therapy, Access gap, Physical health conditions, Inequality

Background and context

Mental health problems account for 13% of disease burden worldwide (Ritchie and Roser, 2018), with the reported experience of mental health difficulties expected to increase globally, and by 2030 be the leading cause of mortality and morbidity (World Health Organization, 2011). A review showed that mental health problems account for 21% of years lived with disability (Global Burden of Disease Study 2013 Collaborators, 2015). The socioeconomic costs of mental ill-health through treatment, social support, and losses to the economy by individuals who cannot work total $1-trillion a year worldwide.

Poor mental health is also associated with physical health difficulties. Worldwide, chronic diseases account for 46% of burden (World Health Organization, 2002). In the United Kingdom (UK), more than 30% of the population have one or more long-term health condition, of which, over 25% also have a mental health difficulty (Naylor et al., 2012). The relationship between physical and mental health is bidirectional, whereby individuals with a physical health problem are at increased risk of developing a mental health problem and vice-versa (van Manen et al., 2002). Physical health disability can prevent people from working, which lowers people's quality of life and increases the impact on health clinics (Kings Fund, 2012). Individual socioeconomic indicators such as employment are associated with living in areas of deprivation (Massey et al., 1991), and it is argued that physical and social environments of neighbourhoods are key to understanding health outcomes (Macintyre et al., 1993). It is important to consider the interaction between deprivation, physical, and mental health as there is the potential for a 'perfect storm' of poor physical health, deprivation, and poor mental health (Diez Roux, 2001).

Deprivation refers to an individual's level of resource in relation to others and is a multifactorial construct that may include factors such as: income, housing, social, recreational, educational, and health-related factors (Adler and Snibbe, 2003, Townsend, 1979). Socioeconomically deprived areas and socioeconomic inequalities are associated with health and social problems such as an increased prevalence of common mental health disorders (Wilkinson and Pickett, 2007, Fryers et al., 2003), and greater demand (number of referrals) for psychological care (Delgadillo et al., 2018). Similar to the relationship between mental and physical health, the relationship between deprivation and mental illness may be bi-directional, as in the social causation (Dohrenwend and

Dohrenwend, 1996) and social selection (Dohrenwend et al., 1992) hypotheses.

Despite increasing need for and use of mental health treatments and treatment providers (McManus et al., 2016), there are inequalities in who receives treatment. In particular, individuals living in lower income households are more likely to have requested mental health treatment than those from higher income households, but were less likely to have accessed or attended treatment (McManus et al., 2016, Saxon et al., 2007).

Socioeconomically deprived areas have lower treatment access rates irrespective of local variations in the availability of therapists (Delgadillo et al., 2018). When individuals of low socioeconomic status or from deprived neighbourhoods do access psychological therapy, evidence consistently suggests that they find therapy less effective (Berzins et al., 2018, Finegan et al., 2018, Delgadillo et al., 2016), with some exceptions, (Silva et al., 2016). These associations have been demonstrated using both individual level and area (or neighbourhood) level measures of deprivation (Finegan et al., 2018). Therefore, it is prudent to ensure that clinicians are supporting those with the most need.

The overwhelming majority of evidence linking deprivation and mental health treatment access and outcomes comes specifically from mental health contexts, whilst less is known about this relationship in physical health contexts where physical and mental health difficulties and deprivation have high rates of co-occurrence. Furthermore, there is little evidence focused on individuals once they are referred to treatment providers (typically, the access gap focuses on the incidence – referral gap). For example, some clinics require people to actively 'opt-in' after referral, and most require them to attend a series of outpatient appointments. If there are inequalities within the care pathway, action may be required of treatment providers to reduce or remove obstacles to those living in deprivation.

Aims

The aim of this evaluation was to use referral and treatment data to investigate the potential effects of neighbourhood deprivation on access to treatment, treatment completion, and clinical outcomes. The evaluation aimed to answer two questions. Firstly, 'are there utilisation inequalities within the health psychology care pathway for individuals living in areas of higher deprivation?''. Secondly, 'does deprivation have an impact on health psychology clinical outcomes?'

Objectives

- use descriptive data to compare the relative distribution of neighbourhood deprivation in the sample with that of estimates for the population served by the clinic.

- test associations between patients' IMD decile and their progress through the care pathway at three points: 1) attendance of assessment appointment; 2) attendance of at least one treatment appointment; and 3) completion of treatment.

- for patients who complete treatment, test the association between patient IMD decile and clinical outcome (measured by reliable change).

Methods

The data were routinely collected by the clinic and anonymised by the routine care team before evaluation. The evaluation was not classified as research and as such, the Health Research Authority (HRA) do not require Research Ethics Committee approval or HRA research approval.

Setting and participants

The health psychology clinic provides psychological care for people with physical health problems across five catchment areas in Derbyshire, UK. Common conditions include chronic pain, chronic fatigue, cancer, coronary heart disease, diabetes, sexual health conditions, neurological conditions, and respiratory disorders. Individuals are referred to the clinic by their General Practitioner (GP) or a health professional involved in their care. A triage process determines the appropriateness of the referral. If the referral is considered appropriate, an *opt-in* letter is sent to the individual, inviting them to opt-in to the clinic. Following opt-in, they are offered an assessment appointment. Treatment decisions are made at the assessment appointment. Typically, this might involve being placed on a waiting list to receive a short series (typically 6-8) of one-to-one follow-up treatment appointments. A small percentage of individuals are expedited for immediate treatment. Interventions delivered via groups, electronically, or by assistant psychologists (e.g., relaxation skills) may also at times be offered in certain circumstances. Discharge is also an option, either with referral to other more suitable treatment providers, or following a decision that no further action is appropriate at that time.

Measures

The Index of Multiple Deprivation (IMD) is the official UK Government measure of relative area-level (neighbourhood) deprivation in England. Here, a neighbourhood is defined as the Lower-Layer Super Output Area (LSOA). Each LSOA is designed to include approximately 1,500 people. The IMD is comprised of seven domains: (a) income, (b) employment, (c) education, skills, and training, (d) health and disability, (e) crime, (f) barriers to housing and services, and (g) living environment. These domains are combined and weighted to produce an overall relative measure of deprivation (IMD) (Department for Communities and Local Government, 2016). The IMD therefore reflects the multifaceted nature of deprivation. IMD scores are then ranked across every LSOA in England from 1 to 32,844 (most to least deprived area). Areas are often described by the percentile or decile of relative deprivation they fall into. Deciles are calculated by dividing the 32,844 ranks into ten equal groups, ranging from most deprived to least deprived. For example, 'the area falls within the most deprived 20% nationally'. In this study, all analyses used IMD deciles. The IMD is often used locally in the development of strategies and to support funding bids (Department for Communities and Local Government, 2016).

The IMD is a relative measure and is only able to tell us that one area is more deprived than another area, but it is unable to tell us by how much. For example, an area with a rank of 500 is not twice as deprived as an area with a rank of 1000. Further, the IMD provides an indication of relative deprivation in a small area, but each area will contain variability in individual deprivation. Finally, the IMD is a measure of aspects of deprivation and not affluence - the income measure of deprivation represents individuals on low incomes who receive benefits and tax credits (Department for Communities and Local Government, 2016).

The Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) (Evans et al., 2000), which is used as a routine outcome measure by the clinic, provides a global measure of distress. The CORE-OM is a generic self-report measure suitable for assessing response to psychological therapy. The CORE-OM is sensitive to change and has high internal and test-retest reliability (Evans et al., 2000). The outcome measure comprises 34-items separated into four subscales (wellbeing, problems, functioning, and risk) and provides an overall mean score. Data were assessed using reliable and clinically significant recovery as indicated by Jacobson et al. (1984).

Other variables included patients' age, sex, ethnicity, referral source, screening outcome, discharge reason, and attendance data.

Data collection

The health psychology clinic routinely seeks to collect all data described in the measures section, except for IMD, which is public data and was linked with patient records. The analysed dataset was drawn from data from all individuals referred to the clinic from the 13th December 2017 to 11th December 2018 (one year). Sample inclusion criteria required that individuals had valid postcode data (in order to match individuals to IMD) and were not still awaiting assessment (and therefore had care pathway data). Data were anonymised within the clinic.

Statistical methods and analysis

Data were quantitative and were collected at nominal, ordinal, and interval level. Data were analysed using IBM SPSS (version 25). Summary statistics were reported in the following areas: demographics of individuals, referral source, attendance, and levels of deprivation.

Distributions were examined using the Kolmogorov-Smirnov and Shapiro-Wilk tests, and histogram examination. Age data were non-normally distributed and were summarised in terms of median and inter-quartile range. IMD decile data were non-normally distributed and were analysed using non-parametric tests such as Spearman's correlation. A linear regression was completed to investigate predictors for the outcome variable. There were no missing data for the regression. All other data were categorical and were summarised by frequency and tests for significance for categorical data. Where counts were less than expected Fisher's Exact test was used. Two-tailed tests were used throughout and the threshold for statistical significance set at 5%.

Clinical outcomes were defined as follows. The reliable change index was used to assess patient outcomes (Guhn et al., 2014). The reliable change index consists of reliable and/or clinically significant recovery. Reliable change is represented by a change of five or more in the clinical score. Clinically significant recovery is indicated when a patient's score moves from the clinical to the non-clinical population. On the CORE-OM clinically significant scores were observed when individuals scored over ten pre-therapy and under ten post-therapy.

In order to provide additional context to the results, demographic and IMD data of those in the clinic were compared to local area profile estimates, using data from the IMD and Office of National Statistics.

Results

A total of 491 referrals were received by the team between the 13th December 2017 and the 11th December 2018. Of those 491 referrals, one individual was excluded due to missing postcode data. Eleven individuals were excluded as they were still awaiting an initial assessment and so had no clinical pathway data. After exclusions 479 individual data remained in the sample and were included in analysis. Summary sample statistics can be seen in Table 15.

Table 15. *Sample summary statistics*

Demographic	*N*=479
Median Age (IQR; Range)	52 (43-61; 17-93)
Females	308 (64.3%)
Ethnicity	White British: 304 (63.5%) Other European (White, Mixed, Unspecified): 3 (0.6%) Other Mixed: 2 (0.4%) Other: 1 (0.2%) Not stated: 169 (35.3%)
Referral source	Acute Hospitals: 218 (45.5%) Community Teams: 35 (7.4%) General/Family Practitioner: 167 (35.0%) Frontline Mental Health Team ("IAPT"): 4 (0.8%) Specialist Mental Health Team: 11 (2.3%) Mental Health Liaison: 40 (8.4%) Older Adult Psychology: 1 (0.2%) Missing: 3 (0.6%)
Status on the 11th December 2018	Not suitable: 4 (0.8%) Did not opt in: 10 (2.1%) Did not attend assessment: 19 (4.0%) Discharged after assessment: 83 (17.3%) Attended assessment awaiting treatment: 100 (20.9%) Treatment in progress: 134 (28.0%) Dropped out of treatment: 46 (9.6%) Completed treatment: 83 (17.3%)
Reason for discharge following assessment (*n*=83)	Not suitable: 12 (14.5%) Referred to other services: 15 (18.1%) Declined treatment: 14 (16.9%) Assessment only required: 42 (50.6%)
Dropped out of treatment reason (*n*=46)	Mental health factors: 7 (15.2%) Physical health factors: 3 (6.5%) Social factors: 5 (10.9%) No known reason: 31 (67.4%)

CORE-OM reliable change - completers only (*n*=83)	Reliable deterioration: 2 (2.4%) Unchanged: 49 (59.0%) Reliable improvement: 32 (38.6%)
CORE-OM recovery - completers only (*n*=83)	No clinically significant recovery: 62 (74.7%) Clinically significant recovery: 21 (25.3%)

CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; IQR = Inter quartile range; IAPT = Increasing Access to Psychological Therapies; IMD = Index of Multiple Deprivation.

Comparison of sample with local population

There are 32,844 small areas across England including 491 in Derbyshire. Each small area contains on average 1,500 people. The clinic covers 282 of these small areas. As can be seen in Table 16, the area of Derbyshire covered by the clinic includes 12 small areas in the first decile (representing the top 10% of deprivation nationally). The majority of the small areas fall into the ninth decile. According to regional data taken from the mid-2015 Office of National Statistics population estimates, there were 444,467 individuals living in the areas covered by the clinic (Office of National Statistics, 2015). Of which there were an estimated 218,343 males and 226,124 females of all ages.

The sample comprised 479 people across all deciles, and all deciles were represented. As seen in Table 16 if each ward were to contain 1500 people, the estimated total representation for Derbyshire is shown and the percentage of representation of the sample is highlighted.

When the number of referrals in the sample was compared to the regional population estimates, there was no evidence of significant under-representation from the most deprived deciles (Table 16). In contrast, the percentage of individuals referred to the clinic who lived in deciles 2 and 3 (more highly deprived) was significantly higher than the estimated percentage of individuals overall living in those highly deprived areas. Similarly, the percentage of referrals from deciles 7 and 9 (less deprived) were significantly under-represented compared with population estimates. There was no significant difference between referrals and population estimates in the remaining 6 deciles.

The average population age of Derbyshire is 42 years. The median age of individuals in the sample was 52 years (IQR 43-61, range 17-93). It should be noted that the clinic only accepts individuals aged over 16 years. The gender split in the Derbyshire area is reported to be 50.9% female. In the sample there were 308 (64.3%) females.

Table 16. *A comparison of service referrals versus population estimates in the service catchment area across levels of deprivation*

Decile	Decile description	LSOAs in service area	Estimated number of individuals living in service area	Percentage of individuals living in service area (%) (*n*=423,000)	Number of individuals referred to the service	Percentage of evaluation sample representing decile (%) (95% CI) (*n*=479)
1	10% most deprived	12	18,000	4.3	30	6.3 (4.0-8.5)
2	10% to 20%	26	39,000	9.2	62	12.9 (9.8-16.1)*
3	20% to 30%	31	46,500	11.0	83	17.3 (13.8-20.8)*
4	30% to 40%	34	51,000	12.1	68	14.2 (11.0-17.4)
5	40% to 50%	30	45,000	10.6	46	9.6 (6.9-12.3)
6	50% to 60%	27	40,500	9.6	41	8.6 (5.9-11.2)
7	60% to 70%	36	54,000	12.8	47	9.8 (7.0-12.6)*
8	70% to 80%	30	45,000	10.6	41	8.6 (5.9-11.2)
9	80% to 90%	38	57,000	13.5	38	7.9 (5.4-10.5)*
10	10% least deprived	18	27,000	6.4	23	4.8 (2.8-6.8)

* = significant difference from population estimate. LSOA = Lower-Layer Super Output Areas. LSOAs are designed so that approximately 1500 individuals live in each LSOA.

Attending assessment, attending treatment, and completing treatment

As seen in Table 17, 33 individuals did not attend assessment; either they did not opt-in, did not attend the initial assessment, or they were not suitable for the clinic. There was no significant association between IMD decile and whether an individual attended assessment or not (Fisher's p= .792). When considering the order of ranks the linear-by-linear association was statistically non-significant (0.480, p= .511). Illustratively, when considering the ranked order of deciles, the logistic regression was statistically non-significant $\chi^2(1)$= 0.481, p= .488. The model explained 0.03% (Nagelkerke R^2) of the variance in attending assessment and correctly classified 93.1% of cases. IMD was not significantly associated with attending assessment β= 0.049, OR= 1.051 (CI 95%= 0.914–1.208), p= .489. As the cell counts were less than 5 in more than 20% of IMD deciles, these results are provided only to support the Fisher's exact test.

There was no significant association between IMD decile and whether or not an individual attended at least one treatment appointment, X^2= (18, n= 479) 22.632, p= .205. When considering the order of ranks the linear-by-linear association was statistically non-significant (0.719, p= .403). The logistic regression was statistically non-significant $\chi^2(1)$= 0.724, p= .395. The model explained 0.03% (Nagelkerke R^2) of the variance in attending treatment and correctly classified 69.4% of cases. IMD was not significantly associated with attending treatment β= 0.037, OR= 1.037 (CI 95%= 0.953–1.129), p= .396, suggesting no association between increasing deprivation and non-attendance.

Finally, there was no statistically significant difference between IMD decile and those that completed versus dropped out of treatment (Fisher's p= .349), or those that completed treatment versus those that did not (including those discharged after assessment and therefore did not start treatment). The model explained <0.001% (Nagelkerke R^2) of the variance in completing treatment and correctly classified 66.1% of cases. IMD was not significantly associated with completing treatment β= 0.009, OR= 1.009 (CI 95%= 0.912–1.116), p= .866, suggesting no association between increasing deprivation and completing treatment.

Treatment effectiveness

Of those who completed treatment (n= 83), reliable improvement was seen in 32 (38.6%) and clinically significant recovery in 21

(25.3%) individuals. Two (2.4%) individuals experienced reliable deterioration. There was no significant association (r_s= -.148, p= .182) between IMD and reliable change on the CORE-OM for individuals who completed treatment. There was no significant association between IMD and post-treatment CORE-OM scores (r_s= .149, p= .200). An intention to treat sensitivity analysis (n= 479) also showed no significant association between IMD and reliable change on the CORE-OM (r_s= -.026, p= .574).

Table 17. *Deprivation by decile and care pathway outcome*

	Decile										
(*n*†)	1	2	3	4	5	6	7	8	9	10	Sig
Attended Assessment (*n*=479)											Fisher's Exact *p*=
Yes:446	28 (6.3%)	56 (12.6%)	76 (17.0%)	64 14.4%)	45 (10.1%)	36 (8.1%)	45 (10.1%)	39 (8.7%)	36 (8.1%)	21 (4.7%)	0.792
No:33	2 (6.1%)	6 (18.2%)	7 (21.2%)	4 (12.1%)	1 (3.0%)	5 (15.2%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	
Post assessment discharge reason (*n*=83)											Fisher's Exact *p*=
Not suitable:12	1 (8.3%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	2 (16.7%)	0 (0.0%)	3 (25.0%)	0 (0.0%)	0.854
Referred to other service:15	1 (6.7%)	1 (6.7%)	1 (6.7%)	3 (20.0%)	3 (20.0%)	2 13.3%	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	
Declined follow up:14	2 (14.3%)	1 (7.4%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	
Assessment only required:42	5 (11.9%)	5 (11.9%)	8 (19.1%)	5 (11.9%)	3 (7.1%)	5 (11.9%)	1 (2.4%)	7 (16.7%)	1 (2.4%)	2 (4.6%)	
Attended at least one session of treatment (*n*=379)											X^2 (9) = 8.315, *p*= 0.503
Yes:263	12 (5.1%)	32 (13.6%)	39 (16.5%)	45 (19.1%)	27 (11.4%)	23 (9.8%)	26 (11.0%)	21 (8.9%)	26 (11.0%)	12 (5.1%)	

No:116	11 (9.5%)	15 (12.9%)	19 (16.4%)	14 (12.1%)	9 (7.6%)	14 (12.1%)	8 (6.9%)	12 (10.3%)	8 (6.9%)	6 (5.2%)	
Completed or dropped out of treatment (*n*=129)											Fisher's Exact *p*= 0.349
Completed:83	5 (6.0%)	8 (9.6%)	14 (16.9%)	13 (15.7%)	9 (10.8%)	8 (9.6%)	7 (8.4%)	8 (9.6%)	9 (10.8%)	2 (2.4%)	
Dropped out:46	2 (4.4%)	4 (8.7%)	7 (15.2%)	10 (21.7%)	3 (6.5%)	0 (0.0%)	9 (19.6%)	3 (6.5%)	6 (13.0%)	2 (4.4%)	
CORE-OM reliable change – completers only (*n*=83)											Fisher's Exact *p*= 0.162
Reliable deterioration:2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	
Unchanged:49	2 (4.1%)	3 (6.1%)	11 (22.5%)	6 (12.2%)	5 (10.2%)	5 (10.2%)	6 (12.2%)	4 (8.2%)	7 (14.3%)	0 (0.0%)	
Reliable improvement:32	3 (9.4%)	5 (15.6%)	3 (9.4%)	7 (21.9%)	3 (9.4%)	3 (9.4%)	1 (3.1%)	4 (12.5%)	2 (6.3%)	1 (3.1%)	
CORE-OM clinically significant recovery – completers only (*n*=83)											Fisher's Exact *p*= 0.570
Not clinically significant:62	4 (6.5%)	5 (8.1%)	13 (21.0%)	9 (14.5%)	7 (11.3%)	6 (9.7%)	6 (9.7%)	4 (6.5%)	7 (11.3%)	1 (1.6%)	
Clinically significant recovery:21	1 (4.8%)	3 (14.3%)	1 (4.8%)	4 (19.1%)	2 (9.5%)	2 (9.5%)	1 (4.8%)	4 (19.0%)	2 (9.5%)	1 (4.8%)	

† percentage of participants by decile

psychological therapy and patient outcomes in a clinic for people with physical health problems. The evaluation arose as a result of growing evidence that increased deprivation negatively impacts attendance at psychological therapy and treatment outcomes. The evaluation was designed to identify the extent of this potential problem in the specific clinic, as well as understand if and where resources and initiatives were required to reduce any gaps or inequalities.

The results of this evaluation showed no significant association between deprivation and psychological therapy access, treatment completion, or clinical outcomes. This is contrary to the majority of evidence (McManus et al., 2016, Finegan et al., 2018), although other studies using IMD have also found no significant association (Firth et al., 2015, Poots et al., 2014).

Saxon et al. (2007) note that although those from areas of higher deprivation are often less represented in psychotherapy samples than those from areas of lower deprivation, some studies have detected no association. They hypothesise that conflicting findings may relate to differences in health systems, or by improvements in accessibility over time (Saxon et al., 2007). The current evaluation found no statistical evidence of under-representation for those from deprived areas. If anything, people from areas of higher deprivation were over-represented compared to locality population estimates, whilst people from areas of lower deprivation were under-represented. There is robust evidence linking deprivation with incidence of mental and physical health conditions (Naylor et al., 2012). As such, if clinics are equitable and accessible to all who need them, we would expect that the patient distribution would be skewed in the direction observed.

These findings are encouraging, in that there was no explicit evidence found in this evaluation to suggest an access gap/inverse care law effect in the clinic's current provision (either by way of a sample skewed towards less deprived areas, or in comparison with locality population estimates of deprivation). However, the current study was not able to rule out a relative access gap by comparing directly with estimates of the prevalence of need across levels of deprivation (in other words, the skew towards deprived areas may be even greater in estimates of need, compared with the current clinic sample). In addition, the current evaluation could only assess equality of access within the specific clinic (rather than the care system as a whole, or other sectors of care such as

Previous research has found that incidence and severity of psychological distress are associated with social and economic inequalities (Bruce et al., 1992, Mirowsky and Ross, 1989, Prilleltensky, 2008). Social processes such as these have been hypothesised to shape identity and reduce self-efficacy in the least privileged individuals (Bourdieu, 1984, Stoppard, 2014, Wilkinson, 1998). We might therefore expect that the clinic would see inequalities across deprivation deciles in referrals and treatment utilisation, which were not identified in the evaluation.

Help-seeking behaviour may help to understand these results. Three factors are critical in help-seeking behaviour - attitudes towards help-seeking, intention to seek help, and actual help-seeking behaviour (Gulliver et al., 2012). Awareness of one's subjective needs also influences the decision of whether or not to seek help (Gross and McMullen, 1983). The theory of planned behaviour (an extension of theory of reasoned action)(Ajzen, 1991) states that an individual's attitude toward behaviour, subjective norms, and perceived behavioural control influence an individual's behaviours. If an individual evaluates a behaviour as positive (attitude), and they believe that other individuals, such as a care team, want them to engage in the behaviour (subjective norm) then the individual's motivation is higher, and they are more likely to engage in the behaviour.

One hypothesis is that these factors differ in physical health focused contexts, compared with mental health contexts. There may be greater validation of help-seeking attitudes, and clearer understanding of subjective needs around physical versus mental ill-health. If individuals are already engaged within a health care system in relation to their physical health, this may impact on their subjective norms, compared with individuals suffering from mental ill-health where a) they are not already engaged with health professionals, b) there might be increased stigma and less understanding of difficulties, and c) where symptoms and consequences of difficulties may be less visible or more nebulous. These motivators may be counteracting the negative impact of deprivation in this evaluation.

This explanation is consistent with the construct of candidacy regarding access to clinics (Dixon-Woods et al., 2006). Candidacy explains how an individual's eligibility for healthcare is determined by healthcare providers and the individual. Candidacy is a continuous process that is defined and

non-engagement or loss of agency.

Strengths and Limitations

This evaluation included over 97% of patients referred to the clinic during the evaluation period. Only one patient was unable to be linked with IMD, which allowed for a comprehensive review of the deprivation data for those accessing the clinic. The evaluation took a pragmatic practice-based approach to analysis, yet employed multiple methods of analysis, increasing the robustness of results.

IMD (2015) scores were mostly calculated based on 2012/13 tax year data. Although consistency over time may be expected in most cases, differences in deprivation of certain small areas may have affected the results to some extent. This report does not explore potential associations between the seven specific domains of deprivation and attendance and outcomes, although the overall IMD uses a weighted combination of all seven domains.

IMD provides a deprivation score for small areas throughout the UK. IMD does not provide information about deprivation to specific individuals. It is therefore possible that an individual referred to the clinic may live in an area rated high in deprivation but be a high earner or highly educated etc., or vice versa. This evaluation therefore considers the contextual effect of neighbourhood, not necessarily the direct deprivation of the individual.

Some deciles are poorly represented, which may result in a masking of interaction in some cases. The small number of individuals from the least 10% deprived areas means the non-significant association in worsening scores should be considered with caution, as low numbers of individuals within deciles reduces power. Deciles were used over quintiles as they are more frequently reported. Correlation analysis was conducted and used the whole data set to consider any relationship which may have been masked by reduced power in the Fishers exact test. Future analyses may benefit from using quintiles.

Implications for practice

Findings from this evaluation do not raise immediate concerns regarding inequality for this clinic. Instead, this clinic appears to be statistically

referrals, and whether physical health psychology patients differ from patients accessing mental health clinics, with regards to health seeking behaviours, subjective norms, or conceptualisations of health. These may potentially inoculate against or counteract negative effects of deprivation. Differences in practice may also be identifiable between these contexts. For example, whether practitioners or patients initiate conversations regarding referral, whether the conversation is focused initially on mental or physical health, etc. Understanding the process of what leads to a referral may allow the clinic to understand if there is still a gap in accessing treatment, or, it may indicate differences of working between referrers. It would also be helpful to explore other factors contributing to observed variability in patient access, completion and clinical outcomes.

Repeating the analysis with an increased sample size, and comparison with more accurate estimates of comorbid physical and mental ill-health may provide stronger evidence of equality or inequality, respectively.

Finally, this evaluation does not suggest that therapists ignore deprivation or social-class disparity when working with individuals (Delgadillo, 2018). The relative equality indicated in this evaluation may only be maintained by conscious efforts to address it, that may be undone if therapists become complacent about the impact of deprivation. Ignoring deprivation in this way may be harmful to therapeutic rapport (Trott and Reeves, 2018). As therapeutic rapport has been shown to improve treatment engagement and outcomes (Karver et al., 2006), it would be interesting to see if acknowledgement of differences in sessions improved treatment utilisation and clinical outcomes.

Data preparation was by NF and LLO. Statistical analysis and writing of the first draft of the article was done by LLO. All listed authors were involved in the preparation, review, and critique of the final manuscript. All authors have approved the final manuscript for submission.

Declaration of Conflicting Interests

The authors declare no potential conflicts of interest with respect to the evaluation, authorship, and/or publication of this article. LLO carried out this work in part fulfilment of the requirements of his Doctorate in Clinical Psychology at the University of Lincoln and the University of Nottingham.

Funding

This evaluation was part funded by a grant by Health Education East Midlands, UK.

ADLER, N. E. & SNIBBE, A. C. 2003. The Role of Psychosocial Processes in Explaining the Gradient Between Socioeconomic Status and Health. *Current Directions in Psychological Science,* 12**,** 119-123.

AJZEN, I. 1991. The theory of planned behavior. *Organizational Behavior and Human Decision Processes,* 50**,** 179-211.

BERZINS, S., BABINS-WAGNER, R. & HYLAND, K. 2018. Relationship of employment status and socio-economic factors with distress levels and counselling outcomes during a recession. *Counselling and Psychotherapy Research,* 18**,** 122-132.

BOURDIEU, P. 1984. Distinction. Translated by Richard Nice. *Cambridge, MA: Harvard Univer*.

BRUCE, M. L., TAKEUCHI, D. T. & LEAF, P. J. 1992. Poverty and psychiatric status: longitudinal evidence from the New Haven Epidemiologic Catchment Area Study. *Archives of general psychiatry,* 48**,** 470-474.

DELGADILLO, J. 2018. Worlds apart: Social inequalities and psychological care. *Counselling and Psychotherapy Research,* 18**,** 111-113.

DELGADILLO, J., ASARIA, M., ALI, S. & GILBODY, S. 2016. On poverty, politics and psychology: the socioeconomic gradient of mental healthcare utilisation and outcomes. *Br J Psychiatry,* 209**,** 429-430.

DELGADILLO, J., FARNFIELD, A. & NORTH, A. 2018. Social inequalities in the demand, supply and utilisation of psychological treatment. *Counselling and Psychotherapy Research,* 18**,** 114-121.

DEPARTMENT FOR COMMUNITIES AND LOCAL GOVERNMENT. 2016. The English Indices of Deprivation 2015 – Frequently Asked Questions (FAQs). Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/579151/English_Indices_of_Depriv

DIXON-WOODS, M., CAVERS, D., AGARWAL, S., ANNANDALE, E., ARTHUR, A., HARVEY, J., HSU, R., KATBAMNA, S., OLSEN, R., SMITH, L., RILEY, R. & SUTTON, A. J. 2006. Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. *BMC Med Res Methodol,* 6**,** 35.

DOHRENWEND, B. P. & DOHRENWEND, B. S. 1996. *Social status and psychological disorder; a causal inquiry.,* New York, NY, Wiley-Interscience.

DOHRENWEND, B. P., LEVAV, I., SHROUT, P. E., SCHWARTZ, S., NAVEH, G., LINK, B. G., SKODOL, A. E. & STUEVE, A. 1992. Socioeconomic status and psychiatric disorders: the causation-selection issue. *Science,* 255**,** 946-52.

EVANS, C., MELLOR-CLARK, J., MARGISON, F., BARKHAM, M., AUDIN, K., CONNELL, J. & MCGRATH, G. 2000. CORE: clinical outcomes in routine evaluation. *Journal of Mental Health,* 9**,** 247-255.

FINEGAN, M., FIRTH, N., WOJNAROWSKI, C. & DELGADILLO, J. 2018. Associations between socioeconomic status and psychological therapy outcomes: A systematic review and meta-analysis. *Depress Anxiety,* 35**,** 560-573.

FIRTH, N., BARKHAM, M., KELLETT, S. & SAXON, D. 2015. Therapist effects and moderators of effectiveness and efficiency in psychological wellbeing practitioners: A multilevel modelling analysis. *Behaviour Research and Therapy,* 69**,** 54-62.

FRYERS, T., MELZER, D. & JENKINS, R. 2003. Social inequalities and the common mental disorders: a systematic review of the evidence. *Soc Psychiatry Psychiatr Epidemiol,* 38**,** 229-37.

GLOBAL BURDEN OF DISEASE STUDY 2013 COLLABORATORS 2015. Global, regional, and national incidence, prevalence, and years lived

GROSS, A. E. & MCMULLEN, P. A. 1983. Models of the help-seeking process. *In:* DEPAULO, B. M., NADLER, A. & FISHER, J. D. (eds.) *New directions in helping: Help-seeking.* New York: Academic Press.

GUHN, M., FORER, B. & ZUMBO, B. D. 2014. Reliable Change Index. *In:* MICHALOS, A. C. (ed.) *Encyclopedia of Quality of Life and Well-Being Research.* Dordrecht: Springer Netherlands.

GULLIVER, A., GRIFFITHS, K. M., CHRISTENSEN, H. & BREWER, J. L. 2012. A systematic review of help-seeking interventions for depression, anxiety and general psychological distress. *BMC Psychiatry,* 12**,** 81.

JACOBSON, N. S., FOLLETTE, W. C. & REVENSTORF, D. 1984. Psychotherapy outcome research: Methods for reporting variability and evaluating clinical significance. *Behavior therapy,* 15**,** 336-352.

KARVER, M. S., HANDELSMAN, J. B., FIELDS, S. & BICKMAN, L. 2006. Meta-analysis of therapeutic relationship variables in youth and family therapy: the evidence for different relationship variables in the child and adolescent treatment outcome literature. *Clin Psychol Rev,* 26**,** 50-65.

KINGS FUND 2012. *Long-term conditions and mental health: The cost of comorbidities,* London, Kings Fund.

MACINTYRE, S., MACIVER, S. & SOOMAN, A. 1993. Area, class and health: should we be focusing on places or people? *Journal of social policy,* 22**,** 213-234.

MASSEY, D. S., GROSS, A. B. & EGGERS, M. L. 1991. Segregation, the concentration of poverty, and the life chances of individuals. *Social Science Research,* 20**,** 397-420.

MCMANUS, S., BEBBINGTON, P., JENKINS, R. & BRUGHA, T. (eds.) 2016. *Mental Health and Wellbeing in England: Adult Psychiatric Morbidity*

NAYLOR, C., PARSONAGE, M., MCDAID, D., KNAPP, M., FOSSEY, M. & GALEA, A. 2012. *Long-term conditions and mental health: the cost of co-morbidities,* London, The King's Fund & Centre for Mental Health.

OFFICE OF NATIONAL STATISTICS. 2015. *Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland* [Online]. https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatesforukenglandandwalesscotlandandnorthernireland. [Accessed 3rd March 2019].

POOTS, A. J., GREEN, S. A., HONEYBOURNE, E., GREEN, J., WOODCOCK, T., BARNES, R. & BELL, D. 2014. Improving mental health outcomes: achieving equity through quality improvement. *International journal for quality in health care,* 26**,** 198-204.

PRILLELTENSKY, I. 2008. The role of power in wellness, oppression, and liberation: The promise of psychopolitical validity. *Journal of community psychology,* 36**,** 116-136.

RITCHIE, H. & ROSER, M. 2018. *Mental Health* [Online]. Available: https://ourworldindata.org/mental-health [Accessed 12th October 2019].

SAXON, D., FITZGERALD, G., HOUGHTON, S., LEMME, F., SAUL, C., WARDEN, S. & RICKETTS, T. 2007. Psychotherapy provision, socioeconomic deprivation, and the inverse care law. *Psychotherapy Research,* 17**,** 515-521.

SILVA, M., LOUREIRO, A. & CARDOSO, G. 2016. Social determinants of mental health: A review of the evidence. *The European Journal of Psychiatry,* 30**,** 259-292.

STOPPARD, J. 2014. *Understanding depression: Feminist social*

TROTT, A. & REEVES, A. 2018. Social class and the therapeutic relationship: The perspective of therapists as clients. A qualitative study using a questionnaire survey. *Counselling and Psychotherapy Research,* 18**,** 166-177.

VAN MANEN, J. G., BINDELS, P. J., DEKKER, F. W., CJ, I. J., VAN DER ZEE, J. S. & SCHADE, E. 2002. Risk of depression in patients with chronic obstructive pulmonary disease and its determinants. *Thorax,* 57**,** 412-6.

WILKINSON, R. 1998. What Health Tells Us About Society. *IDS Bulletin,* 29**,** 77-85.

WILKINSON, R. G. & PICKETT, K. E. 2007. The problems of relative deprivation: why some societies do better than others. *Soc Sci Med,* 65**,** 1965-78.

WORLD HEALTH ORGANIZATION. 2002. *The world health report 2002 - Reducing Risks, Promoting Healthy Life* [Online]. Available: https://www.who.int/whr/2002/en/ [Accessed 12th October 2019].

WORLD HEALTH ORGANIZATION. 2011. *Global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level: Report by the Secretariat* [Online]. Available: apps.who.int/gb/ebwha/pdf_files/EB130/B130_9-en.pdf [Accessed 12th October 2019].

WORLD HEALTH ORGANIZATION. 2019. *Mental health in the workplace* [Online]. Available: https://www.who.int/mental_health/in_the_workplace/en/ [Accessed 12th October 2019].